UNITED STATES DISTRICT COURT
DISTRICT OF PUERTO RICO

MUNICIPALITY OF SABANA GRANDE, and MUNICIPALITY OF CAYEY, on behalf of themselves and others similarly situated, Plaintiffs, v. PURDUE PHARMA L.P.; PURDUE PHARMA, INC.; THE PURDUE FREDERICK COMPANY, INC.; TEVA PHARMACEUTICAL INDUSTRIES, LTD.; TEVA PHARMACEUTICALS USA, INC.; CEPHALON, INC.; JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INC.; ORTHO- MCNEIL-JANSSEN PHARMACEUTICALS, INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; JANSSEN PHARMACEUTICA INC. n/k/a JANSSEN PHARMACEUTICALS, INC.; NORAMCO, INC.; ENDO HEALTH SOLUTIONS INC.; ENDO PHARMACEUTICALS, INC.; ALLERGAN PLC f/k/a ACTAVIS PLS; WATSON PHARMACEUTICALS, INC. n/k/a ACTAVIS, INC.; WATSON LABORATORIES, INC.; ACTAVIS LLC; ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC.; MALLINCKRODT PLC; MALLINCKRODT LLC; AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.; and MCKESSON CORPORATION. Defendants.	)	CIVIL ACTION NO. _____ **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

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INTRODUCTION

1. Since morphine was first isolated for medicinal use, physicians have understood that opioids are risky medications that leave patients prone to addiction and overdose. That is why heroin was made illegal in 1924, and it is why the first synthetic opioids (Percocet and Vicodin) were prescribed only for short-term pain.

2. But after Purdue created and patented oxycodone in the 1990s, it marketed the drug as safe, non-addictive, and appropriate for chronic pain—even though it had no legitimate scientific evidence to support these claims. And as other opioid manufacturers likewise invented proprietary opioid formulations, they also marketed their drugs as safe, non-addictive, and appropriate for chronic pain.

3. The opioid manufacturers ran a decades-long misinformation campaign to convince doctors and patients everywhere that prescription opioids are a miracle cure for chronic pain, and should be prescribed widely—whether to treat recurring pain from work injuries, joint pain from arthritis, or neck pain resulting from a car accident.

4. To win over those who might be skeptical of the drug makers' claims, the manufacturers hired well-regarded doctors, who styled themselves as pain management experts, to advocate for use of opioids all across the country. They also sponsored "pain advocacy" groups, which acted as fronts for the drug companies' message. These same tactics were used by cigarette manufacturers, who used industry-funded scientists and front groups to try to convince the public that cigarettes were safe, despite a wealth of scientific evidence to the contrary.

5. Doctors believed the misinformation that was carefully and systematically presented to them over the years. Believing that the opioids were indeed safe and effective for chronic pain, doctors prescribed the opioid manufacturers' products in larger and larger numbers.

6. Meanwhile, the opioid manufacturers knew that their claims lacked scientific basis and that, in fact, their prescription opioids were highly addictive and ultimately ineffective at treating long-term pain. Pain patients develop tolerance to the drugs over time and are forced to take stronger and stronger doses, until they become so sedated that they risk falling asleep at the wheel of their car or having their central nervous system (and breathing) shut down.

7. As doctors prescribed more and more prescription opioids, and the manufacturers continued to conceal and obscure the truth about their drugs, the rates of opioid addiction and overdose skyrocketed. Addicted individuals spent their life savings fueling their drug addiction and were often forced to switch to a cheaper opioid: heroin. Rates of heroin addiction skyrocketed as well.

8. Rather than seeing a national crisis, pharmaceutical distributors saw an opportunity for massive profits. They sent prescription opioids to any and every prescriber or pharmacy who placed orders, even though they are required by federal law to stop shipment on suspicious orders and report them to law enforcement. Stopping suspicious shipments would mean losing out on millions of dollars in illicit profits, and so the opioid distributors did nothing. They stood aside and allowed select prescribers and pharmacies to divert massive amounts of prescription opioids into the black market.

9. The opioid epidemic has enriched both opioid manufacturers and distributors. But it has destroyed communities, and left state and local governments to bear much of the costs. For example, state-funded healthcare costs surged as overdose patients were increasingly admitted to emergency rooms across the country. So did law-enforcement and criminal-justice costs, as police and jails struggled to cope with an increased number of drug offenders. And as addicted

parents are unable to care for their children, the government has often been forced to pay the cost of raising them.

10. It is time that the opioid manufacturers and distributors begin paying for the havoc they have wrought. On behalf of themselves and other municipalities in Puerto Rico, Plaintiffs bring this lawsuit to enjoin Defendants' illegal conduct and to hold Defendants responsible for the harm that conduct has caused the cities and towns of Puerto Rico.

11. With many of Puerto Rico's cities and towns dealing with the aftermath of Hurricane Maria, the worst national disaster in Puerto Rico's history, Plaintiffs believe that a class action will be the most efficient and effective manner of prosecuting Defendants' illegal conduct. They ask that the Court certify this case as a class action on behalf of all of Puerto Rico's municipalities, and award the class-member municipalities damages and injunctive relief according to proof.

PARTIES

A. PLAINTIFFS

12. The Municipality of Sabana Grande is a governmental entity formed as a municipality within and in accordance with the laws of the Commonwealth of Puerto Rico.

13. The Municipality of Cayey is a governmental entity formed as a municipality within and in accordance with the laws of the Commonwealth of Puerto Rico.

B. DEFENDANTS

1. Opioid Manufacturers

14. The defendants within this subsection will be referred to throughout as the "Opioid Manufacturers."

Purdue Defendants

15. Purdue Pharma L.P. is a limited partnership that is organized under the laws of Delaware and is licensed by the Puerto Rico Department of Health to operate as a drug manufacturer and distributor.

16. Purdue Pharma Inc. is a New York corporation with its principal place of business in Stamford, Connecticut.

17. The Purdue Frederick Company is a Delaware corporation with its principal place of business in Stamford, Connecticut. The company is registered with the Puerto Rico Secretary of State to do business in Puerto Rico.

18. The Purdue defendants will be referred to collectively as "Purdue."

19. Purdue manufactures, promotes, sells, and distributes opioids, such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER, in the United States. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales revenue from OxyContin in the U.S. has fluctuated between $2.47 billion and $2.99 billion. The sales revenue from OxyContin has quadrupled since 2006. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (painkillers).

Cephalon Defendants

20. Cephalon Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania, and is registered with the Puerto Rico Secretary of State to do business in Puerto Rico. The company is licensed by the Puerto Rico Department of Health to manufacture, label, repackage, or distribute prescription drugs and controlled substances in Puerto Rico.

21. Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. In 2011, Teva Ltd. acquired Cephalon, Inc.

22. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania, and is registered with the Puerto Rico Secretary of State to do business in Puerto Rico. Teva USA is licensed by the Puerto Rico Department of Health to distribute prescription drugs and controlled substances in Puerto Rico. Teva USA is a wholly owned subsidiary of Teva Ltd.

23. Cephalon, Inc. manufactures, promotes, sells, and distributes opioids such as Actiq and Fentora in the United States. Actiq has been approved by the FDA only for the "management of breakthrough cancer pain in patients 16 years and older with malignancies who are already receiving and who are tolerant to around-the-clock opioid therapy for the underlying persistent cancer pain."[1] Fentora has been approved by the FDA only for the "management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain."[2] In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug and Cosmetic Act for its misleading promotion of Actiq and two other drugs, and agreed to pay $425 million.[3]

24. Teva Ltd., Teva USA, and Cephalon, Inc. work together closely to market and sell Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for Cephalon in the United States through Teva USA and has done so since its October 2011 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products to the public. Teva USA sells all former Cephalon branded products through its "specialty medicines" division. The FDA-approved prescribing information and medication guide, which is

[1] Highlights of Prescribing Information, ACTIQ® (fentanyl citrate) oral transmucosal lozenge, CII (2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf.
[2] Highlights of Prescribing Information, FENTORA® (fentanyl citrate) buccal tablet, CII (2011), https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf.
[3] Press Release, U.S. Dep't of Justice, Biopharmaceutical Company, Cephalon, to Pay $425 Million & Enter Plea to Resolve Allegations of Off-Label Marketing (Sept. 29, 2008), https://www.justice.gov/archive/opa/pr/2008/September/08-civ-860.html.

distributed with Cephalon opioids, discloses that the guide was submitted by Teva USA, and directs physicians to contact Teva USA to report adverse events.

25. All of Cephalon's promotional websites, including those for Actiq and Fentora, display Teva Ltd.'s logo.[4] Teva Ltd.'s financial reports list Cephalon's and Teva USA's sales as its own, and its year-end report for 2012 – the year immediately following the Cephalon acquisition – attributed a 22% increase in its specialty medicine sales to "the inclusion of a full year of Cephalon's specialty sales," including *inter alia* sales of Fentora®.[5] Through interrelated operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon and Teva USA. The United States is the largest of Teva Ltd.'s global markets, representing 53% of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Inc., Teva Ltd. would conduct those companies' business in the United States itself. Teva Ltd. directs the business practices of Cephalon and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder.

26. Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., and Cephalon, Inc. will be referred to collectively as "Cephalon."

Janssen Defendants

27. Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey. Janssen Pharmaceuticals, Inc. is licensed by the Puerto Rico Department of Health to distribute prescription drugs and controlled substances in Puerto Rico. Janssen Pharmaceuticals, Inc. is a wholly owned subsidiary of Johnson & Johnson ("J&J"), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

[4] *E.g.*, ACTIQ, http://www.actiq.com/ (displaying logo at bottom-left).
[5] Teva Ltd., Annual Report (Form 20-F) 62 (Feb. 12, 2013), http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2 012.pdf.

28. Noramco, Inc. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware. Noramco is licensed by the Puerto Rico Department of Health as a manufacturer or repackager/labeler of prescription drugs and controlled substances. Noramco was a wholly owned subsidiary of J&J until July 2016.

29. Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, Inc. are companies that are now known as "Janssen Pharmaceuticals, Inc."

30. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals, Inc.'s stock, and corresponds with the FDA regarding Janssen Pharmaceuticals, Inc.'s products. J&J controls the sale and development of Janssen Pharmaceuticals, Inc.'s drugs, and Janssen Pharmaceuticals, Inc.'s profits inure to J&J's benefit.

31. Janssen Pharmaceuticals, Inc., Ortho-McNeil-Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Noramco, and J&J will be referred to collectively as "Janssen."

32. Janssen manufactures, promotes, sells, and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed, and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

Endo Defendants

33. Endo Health Solutions Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

34. Endo Pharmaceuticals Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a wholly owned subsidiary of Endo Health Solutions Inc. Endo Pharmaceuticals Inc. is registered with the Puerto Rico

Secretary of State to do business in Puerto Rico, and is licensed by the Puerto Rico Department of Health to distribute prescription drugs and controlled substances in Puerto Rico.

35. Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. will be referred to collectively as "Endo."

36. Endo develops, markets, and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet, and Zydone, in the United States. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 to 2013, and it accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

Actavis Defendants

37. Allergan plc is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Allergan plc is the product of a few acquisitions and mergers. In March 2015, Allergan plc was acquired by Actavis plc, and the combined company took the name "Allergan plc." Actavis plc was itself the product of an acquisition: in October 2012, Watson Pharmaceuticals, Inc.'s acquired Actavis, Inc., and the combined company adopted the name "Actavis plc."

38. Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is registered with the Puerto Rico Secretary of State to do business in Puerto Rico. Watson Laboratories, Inc. is a wholly-owned subsidiary of Allergan plc.

39. Actavis Pharma, Inc. is a Delaware corporation with its principal place of business in New Jersey. Actavis Pharma, Inc. is registered with the Puerto Rico Secretary of

State to do business in Puerto Rico, and is licensed by the Puerto Rico Department of Health as a distributor of prescription drugs and controlled substances. Actavis Pharma, Inc. was formerly known as Watson Pharma, Inc.

40. Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey, and is licensed by the Puerto Rico Department of Health as a manufacturer, labeler, or repackager of prescription drugs and controlled substances.

41. Each of the Actavis defendants is owned by Allergan plc, which uses them to market and sell its drugs in the United States. Allergan plc exercises control over these marketing and sales efforts, and profits from the sale of Allergan/Actavis products ultimately inure to its benefit.

42. Allergan plc, Actavis plc, Actavis, Inc., Actavis LLC, Actavis Pharma, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Watson Laboratories, Inc. will be referred to collectively as "Actavis."

43. Actavis manufactures, promotes, sells, and distributes opioids, including the branded drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana, in the United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on December 30, 2008, and began marketing Kadian in 2009.

Mallinckrodt Defendants

44. Mallinckrodt, plc is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri.

45. Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware, and is registered with the Puerto Rico Secretary of State to do business in Puerto Rico. Since 2013, Mallinckrodt, LLC has been a wholly owned subsidiary of Mallinckrodt, plc. Prior to 2013, Mallinckrodt, LLC was a wholly-owned subsidiary of the Irish public limited company Covidien pllc (formerly known as Tyco Healthcare).

46. Mallinckrodt, plc and Mallinckrodt, LLC will be referred to collectively as "Mallinckrodt."

47. Mallinckrodt manufactures, markets, and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers, and opioids sold since at least June 2009 under the brand names Exalgo (hydromorphone), Xartemis (oxycodone/acetaminophen) and Roxicodone (oxycodone) (known by the street names "M," "roxies/roxys," or "blues"). In July 2017 Mallinckrodt agreed to pay $35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

2. Opioid Distributors

48. The opioid distributor defendants ("Opioid Distributors") are: McKesson Corporation, Cardinal Health, Inc., and Amerisourcebergen Drug Corporation.

49. At all relevant times, the Opioid Distributors have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Distributors universally failed to comply with federal, state

and Commonwealth law. The Opioid Distributors are engaged in "wholesale distribution," as defined under federal, state and Commonwealth law. Plaintiffs allege the unlawful conduct by the Opioid Distributors is responsible for the volume of prescription opioids plaguing Plaintiffs' and the class's communities.

50. McKesson Corporation ("McKesson") is a Delaware corporation with its principal place of business located in San Francisco, California. McKesson is registered with the Puerto Rico Secretary of State to do business in Puerto Rico, and is licensed by the Puerto Rico Department of Health to distribute prescription drugs and controlled substances in Puerto Rico. At all relevant times, McKesson operated as a nationwide pharmacy wholesaler.

51. Cardinal Health, Inc. ("Cardinal") is an Ohio corporation with its principal office in Dublin, Ohio. At all relevant times, Cardinal operated as a licensed pharmacy wholesaler in Puerto Rico.[6] Cardinal Health is licensed by the Puerto Rico Department of Health to label, repackage, and distribute prescription drugs and controlled substances. Cardinal's wholly-owned subsidiary Cardinal Health 120 operates a wholesale drug distribution center licensed by the Puerto Rico Department of Health to operate as a distributor of prescription drugs and controlled substances in Puerto Rico.

52. Amerisourcebergen Drug Corporation ("AmerisourceBergen") is a Delaware corporation with its principal place of business is in Chesterbrook, Pennsylvania. AmerisourceBergen is registered with the Puerto Rico Secretary of State to do business in Puerto Rico. At all relevant times, AmerisourceBergen operated as a nationwide pharmacy wholesaler. AmerisourceBergan maintains wholesale drug distribution centers licensed by the Puerto Rico Department of Health to operate as a distributor of prescription drugs and controlled substances in Puerto Rico.

[6] Cardinal has registered its subsidiaries for business in Puerto Rico, including Cardinal Health 120, Inc.

53. The data which reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. *See Madel v. USDOJ*, 784 F.3d 448 (8th Cir. 2015). Neither the DEA nor the wholesale distributors will voluntarily disclose the data necessary to identify with specificity the transactions which will form the evidentiary basis for the claims asserted herein.[7, 8]

54. Consequently, Plaintiffs have named the three wholesale distributors (i.e., AmerisourceBergen Drug Corporation, Cardinal Health, Inc., and McKesson Corporation) which dominate 85% of the market share for the distribution of prescription opioids. The "Big 3" are Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 37 (D.D.C. 1998) (describing Cardinal Health, Inc., McKesson Corporation, and AmerisourceBergen Drug Corporation predecessors). Each has been investigated and/or fined by the DEA for the failure to report suspicious orders. Plaintiffs have reason to believe each has engaged in unlawful conduct which resulted in the diversion of prescription opioids into their communities and that discovery will likely reveal others who likewise engaged in unlawful conduct. Plaintiffs name each of the "Big 3" herein as defendants and place the industry on notice that Plaintiffs are acting to abate the public nuisance plaguing their communities. Plaintiffs will request expedited discovery pursuant to Rule 26(d) of the Federal Rules of Civil Procedure to secure the data necessary to reveal and/or confirm the identities of the wholesale distributors, including data from the ARCOS database.

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[7] *See* Declaration of Katherine L. Myrick, Chief, Freedom of Information (FOI)/Privacy Act Unit ("SARF"), FOI, Records Management Section ("SAR"), Drug Enforcement Administration (DEA), United States Department of Justice (DOJ), Madel v. USDOJ, Case 0:13-cv-02832-PAM-FLN, (Document 23) (filed 02/06/14) (noting that ARCOS data is "kept confidential by the DEA").

[8] *See* Declaration of Tina Lantz, Cardinal Health VP of Sales Operation, Madel v. USDOJ, Case 0:13-cv-02832-PAM-FLN, (Document 93) (filed 11/02/16) ("Cardinal Health does not customarily release any of the information identified by the DEA notice letter to the public, nor is the information publicly available. Cardinal Health relies on DEA to protect its confidential business information reported to the Agency.").

JURISDICTION & VENUE

55. This Court has jurisdiction over this action in accordance with 28 U.S.C. § 1332(a), because the Plaintiffs are citizens of the Commonwealth of Puerto Rico and the named Defendants are citizens of different states, and the amount in controversy as to their non-class claims exceeds $75,000, exclusive of interest and costs.

56. This Court has personal jurisdiction over Defendants because they conduct business in the Commonwealth, purposefully direct or directed their actions toward the Commonwealth, some or all consented to be sued in the Commonwealth by registering an agent for service of process, they consensually submitted to the jurisdiction of the Commonwealth when obtaining a manufacturer or distributor license, and because they have the requisite minimum contacts with the Commonwealth necessary to constitutionally permit the Court to exercise jurisdiction.

57. This Court also has personal jurisdiction over all of the defendants under 18 U.S.C. 1965(b). This Court may exercise nationwide jurisdiction over the named Defendants where the "ends of justice" require national service and Plaintiffs demonstrate national contacts. Here, the interests of justice require that Plaintiffs be allowed to bring all members of the nationwide RICO enterprise before the court in a single trial.[9]

58. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 18 U.S.C. §1965, because a substantial part of the events or omissions giving rise to the claim occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claim of relief in this District. 28 U.S.C. § 1391(b); 18 U.S.C. §1965(a).

[9] *See, e.g.*, Iron Workers Local Union No. 17 Insurance Fund v. Philip Morris Inc., 23 F. Supp. 2d 796 (1998) (citing LaSalle National Bank v. Arroyo Office Plaza, Ltd., 1988 WL 23824, *3 (N.D. Ill. Mar 10, 1988); Butcher's Union Local No. 498 v. SDC Invest., Inc., 788 F.2d 535, 539 (9th Cir. 1986).

FACTUAL BACKGROUND

A. The Opioid Epidemic Caused By Defendants

59. Opioids are a class of "analgesic," which are drugs that treat pain or tissue irritation. Tylenol and aspirin are analgesics, but opioids are much more powerful. The dangers of opioid addiction have long been known. During the Civil War, injured soldiers treated with morphine often became addicted.[10] "In 1898, the Bayer Co. started production of another opioid, heroin, on a commercial scale. From its first clinical trials, it was considered a 'wonder drug.'"[11] But soon, people became addicted, and addicts learned that they could get a more intense high from injecting it.[12] When the opioids Percocet and Vicodin came on the market in the mid-to-late 1970s, physicians understood the dangers of addiction, and these drugs were only seen fit for the management of short-term pain, such as from surgery, or to ease the suffering of the terminally ill. But, when the Opioid Manufacturers began inventing their patented opioids in the 1990s, they sought to convince the medical community and the world that opioids were safe and effective for all types of pain, including chronic lower-back pain and arthritis.

60. Unfortunately, the Opioid Manufacturers' misinformation campaign was wildly successful and spurred an opioid epidemic in the United States, the worst drug epidemic in the nation's history. The past two decades in the United States have been characterized by a dramatic increase in the diversion of opioids from licensed prescribers and pharmacies to the illegal market.[13]

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[10] Sonia Moghe, Opioid history: From 'wonder drug' to abuse epidemic, CNN (Oct. 14, 2016), http://cnn.it/1X4yjE9.
[11] *Id.*
[12] *Id.*
[13] *See* Dart, RC, et al., Trends in Opioid Analgesic Abuse and Mortality in the United States, 372 N. Eng. J. Med. 241 (2015).

61. Fueled by legal and illegal sales, the Opioid Manufacturers and Distributors collectively generated $8 billion per year in revenue from prescription opioids, as of 2009.[14]

62. By 2010, enough prescription opioids were sold to medicate every adult in the United States with a dose of 5 milligrams of hydrocodone every 4 hours for 1 month.[15] For each 100 American citizens, 80 opioid prescriptions were issued each year.[16]

63. By 2011, the U.S. Department of Health and Human Services, and the Centers for Disease Control and Prevention declared prescription painkiller overdoses at epidemic levels.

64. Approximately 5,500 people begin misusing prescription opioids every day.[17]

65. In 2016, the President of the United States declared an official opioid epidemic.[18]

1. Puerto Rico's Opioid Epidemic

66. The abuse of prescription and non-prescription opioids is a public health crisis in Puerto Rico. "For decades, Puerto Rico has battled an epidemic of addiction," with fentanyl emerging as the opioid drug-of-choice "in recent years."[19]

67. Most recently, the "overall amount of opioid pain relievers distributed in Puerto Rico [has] increased by 68%" in the short span from 1999 to 2013.[20] During that period,

[14] *See* Katherine Eban, OxyContin: Purdue Pharma's Painful Medicine, Fortune, Nov. 9, 2011, http://for.tn/2DwlUnm; David Crow, Drugmakers Hooked on $10bn Opioid Habit, Fin. Times, Aug. 10, 2016, http://on.ft.com/2zeDbOG.
[15] Katherine M. Keyes at al., Understanding the Rural-Urban Differences in Nonmedical Prescription Opioid Use and Abuse in the United States, 104 Am. J. Pub. Health e52 (2014).
[16] Data for 2010. Ctrs. for Disease Control and Prevent, Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015 (July 7, 2017), https://www.cdc.gov/mmwr/volumes/66/wr/mm6626a4.htm.
[17] *See* Press Release, Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Prescription Painkiller Overdoses at Epidemic Levels (Nov. 1, 2011), https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.
[18] See Proclamation No. 9499, 81 Fed. Reg. 65,173 (Sept. 16, 2016) (proclaiming "Prescription Opioid and Heroin Epidemic Awareness Week").
[19] David Ovalle, Puerto Rico opioid users get less help after Hurricane Maria, Miami Herald (Oct. 23, 2017), http://bit.ly/2DtOndJ.
[20] Felix SEB, Mack Keith Altman, Jones CM, Trends in the Distribution of Opioids in Puerto Rico, 1999-2013. P.R. Health Sci J. (Sept. 2016), 35(3):165-9, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5683078/.

distribution of three types of opioids—fentanyl, hydromorphone, and oxycodone—skyrocketed by 293%, 614%, and 101% respectively.[21]

68. The figure below displays the massive increase in the amount of opioids distributed (and consumed) in Puerto Rico from 1999 to 2013:

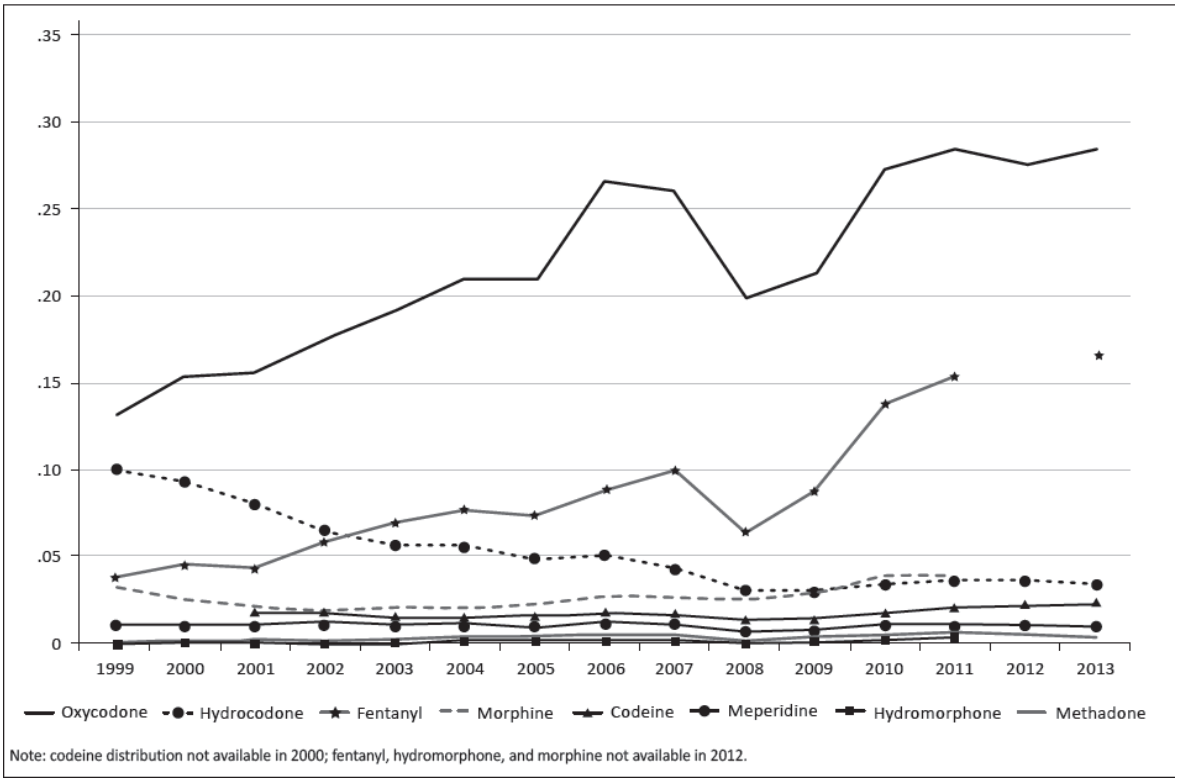


Figure: Amount of Opioids Distributed Annually in Puerto Rico, 1999 to 2013

69. The effect of the opioid crisis in Puerto Rico has only been exacerbated by Hurricane Maria, the worst natural disaster on record in Puerto Rico. The *Miami Herald* reports, "The trio of workers on the relief mission drove through the mountains to deliver supplies to the destitute in a rural region ravaged by Hurricane Maria. But they weren't delivering fuel, ice or hot meals. Instead, the workers, from an organization called Mountain Point, brought packets of clean syringes …. In the wake of the storm, their goal is to keep opioid users—Puerto Rico has a

[21] *Id.*

long-running addiction crisis—free from deadly diseases they could get from injecting drugs."[22] "The toll of Hurricane Maria has added another layer of misery for the tens of thousands of opioid users who dwell in Puerto Rico … and for the small number of dedicated groups who try to help them get clean."[23]

B. The Opioid Manufacturers' Misinformation Campaign

70. The opioid epidemic did not happen by accident; it was foreseen and purposefully fueled by those in a position to profit from a far greater demand and consumption of the drugs than is medically appropriate.

71. Before the 1990s, generally accepted standards of medical practice dictated that opioids should only be used in the short-term. Accepted uses for opioids were to treat acute pain, such as from surgery, cancer, or other terminal illness. The medical community discouraged and prohibited the use of opioids for chronic pain, such as from arthritis or injury. There is insufficient evidence that opioids improve chronic-pain sufferers' ability to function. And there is abundant evidence that chronic-pain patients develop a tolerance over time, so opioids no longer alleviate their symptoms. The lack of benefit for prescribing opioids to sufferers of chronic pain, in other words, was easily outweighed by the serious risk of addiction that stems from persistent use of opioid painkillers.

72. But to improve sales and ensure their drugs reached a wider audience, the Opioid Manufacturers engaged in a marketing scheme designed to persuade doctors and patients that opioids could safely and beneficially be used to treat chronic pain. As part of this scheme, each Opioid Manufacturer spent millions of dollars on promotional activities and materials that falsely

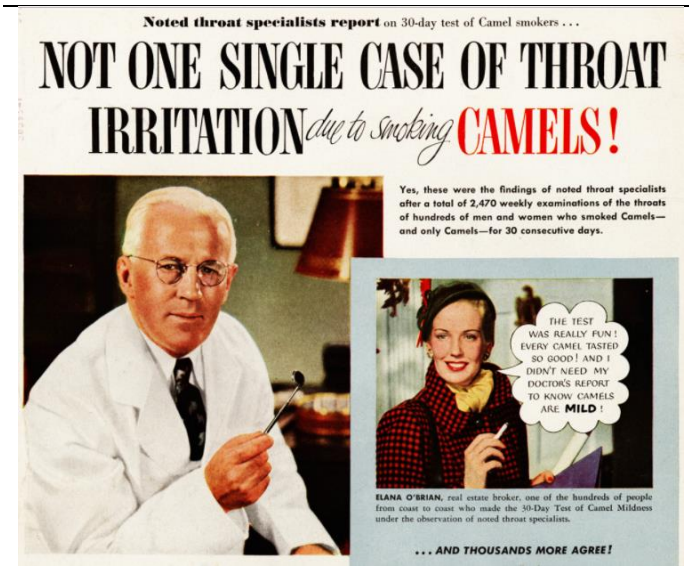
[22] David Ovalle, Puerto Rico opioid users get less help after Hurricane Maria, Miami Herald (Oct. 23, 2017), http://bit.ly/2DtOndJ.
[23] *Id.*

denied or trivialized the risks of opioids, while overstating the benefits of using them for chronic pain.

73. This misinformation scheme was wildly successful, to the widespread detriment of patients. Opioids are now the most prescribed class of drugs. In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors . . . [m]any of [whom] were even taught–incorrectly–that opioids are not addictive when prescribed for legitimate pain."[24] This epidemic has resulted in a flood of prescription opioids available for illicit use (i.e., a supply spike), and a population of patients physically and psychologically dependent on them (i.e., a demand spike). And when those patients can no longer afford or obtain opioids from licensed dispensaries, they often turn to the street to buy prescription opioids or even non-prescription opioids, like heroin.

74. The Opioid Manufacturers used many of the same tactics as the tobacco industry in the late 1950s through the 1980s.[25] The tobacco industry ran direct advertising that misrepresented the dangers of smoking:

[24] Letter from Vivek H. Murthy, U.S. Surgeon General (Aug. 2016), http://turnthetiderx.org/.
[25] Loddenkemper R, Kreuter M (eds), The Tobacco Epidemic, ed 2, rev. and ext. Prog. Respir Res. Basel, Karger, 2015, vol 42, pp. 14, *available at* http://bit.ly/2BKwB5x.



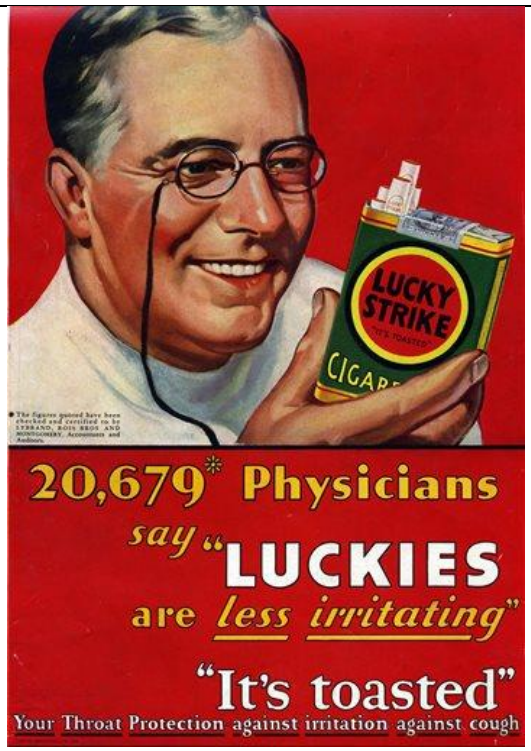


Figure: Cigarette Advertisements

75. Once the public stopped believing these blatantly misleading ads, the tobacco industry touted "safer" formulations of cigarettes, such as filtered cigarettes, low-tar varieties, and light cigarettes.[26]

76. Lastly, the tobacco industry used indirect strategies to mask their role in crafting the message, as part of a decades-long conspiracy "revealed through analysis of the formerly secret internal documents of the industry," acquired in litigation.[27] The cigarette manufacturers "used front groups and artificially created 'grass roots' movements that create[d] the illusion of support" for cigarettes.[28] Most famously, the tobacco industry used the Tobacco Institute to release publications from a seemingly non-biased source to question the scientific consensus about cigarettes and fund scientific research attempting to show cigarettes were safe.

[26] Loddenkemper, *supra* note 25.
[27] *Id.*
[28] *Id.*

77. Similarly, the Opioid Manufacturers used direct advertisements to market opioids as safe and effective to treat chronic pain. As this false messaging became less effective, the Opioid Manufacturers introduced supposedly safer versions of their drugs, such as extended release and crush-resistant formulations, and versions that were only part opioid and part acetaminophen (Tylenol). These formulations were actually more dangerous, as drug abusers began overdosing on the Tylenol or the chemicals in the crush-resistant pill coating. The FDA recently capped the acetaminophen dose that can be used in opioid painkillers and forced Endo to remove its crush-resistant opioid, Opana ER, from the market. Lastly, the Opioid Manufacturers used indirect marketing tactics, hiring influential doctors to advocate that opioids were safe to use for chronic pain, and employing seemingly non-biased front groups to parrot their messages about opioids.

1. Direct Marketing

78. Each Opioid Manufacturer conducted advertising campaigns touting the purported benefits of their branded opioid drugs. For example, the Opioid Manufacturers spent more than $14 million in 2011 alone to advertise opioids in medical journals, nearly triple what they spent 10 years earlier.

79. Many of the Opioid Manufacturers' ads deceptively portrayed benefits of opioids for chronic pain. For example, Endo distributed and made available on its website opana.com a pamphlet promoting Opana ER as a chronic-pain treatment, with photographs depicting patients able to return to physically demanding jobs like construction worker, chef, and teacher, conveying the false message that opioids were a safe and effective way for chronic-pain sufferers to restore their former functionality.

80. Purdue created a promotional video in 1998 called "I got my life back," featuring seven patients whose lives were "turned around by the magic of OxyContin."[29] One patient, Lauren Cambra, was featured as saying that OxyContin had fixed her chronic pain and restored her ability to function.

Figure: Purdue's "I got my life back" advertisement[30]

81. In the ad, Lauren is features as saying, "Since I've been on this new pain medication, I have not missed one day of work, and my boss really appreciates that: 'Lauren is there everyday.' So, I'm able to be very productive. And one of the things … which I'm especially excited about is just the fact that I'm able to spend time with my grandchildren. It's amazing just to be able to keep up with them and not have to always tell them: 'Grandma can't

[29] Jon Oliver, Opioids, Last Week Tonight (Oct. 23, 2016), *available at* https://www.youtube.com/watch?v=5pdPrQFjo2o.
[30] *Id.*

play now; grandma can't do this; … grandma's back hurts.'"[31] The video features heartwarming footage of Ms. Cambra playing with her grandkids.

82. In a follow-up study in 2012 by Physicians for Responsible Opioid Prescribing, entitled "OxyContin Poster Children 15 Years Later," Ms. Cambra said that she became addicted to OxyContin soon after she started taking it, with terrible consequences. She says, "I lost my house; I've lost cars; … I lost a lot to keep taking that drug; … I lost my job."[32] When Ms. Cambra lost her job, she also lost her health insurance. Cambra says, "Had I not lost my medical insurance, otherwise, I would [still] go to the mailbox once a month, and I would find a bottle of OxyContin in it, and I'd probably still be on it, [or] I'd probably be dead."

83. In 2012, the same year that "OxyContin Poster Children 15 Years Later" came out, Purdue ran another series of ads in medical journals. The ad campaign was called "Pain vignettes." These ads featured chronic pain patients and recommended OxyContin to treat their

[31] *Id.*
[32] *Id.*

pain. One ad described a "54-year-old writer with osteoarthritis of the hands" and implied that OxyContin would allow the writer to work again without pain.

84. Unfortunately, well-meaning doctors who wanted to help their pain patients were duped into prescribing OxyContin for long-term pain management. David Juurlink, who runs the division of clinical pharmacology and toxicology at the University of Toronto, explains why these advertisements convinced so many physicians to prescribe OxyContin for chronic pain, "You've got a patient in pain, you've got a doctor who genuinely wants to help, and now suddenly you have an intervention that—we are told—is safe and effective."[33] Keith Humphreys, a professor of psychiatry at Stanford, who served as a drug-policy adviser to the Obama Administration, says of Purdue's marketing efforts, "That's the real Greek tragedy of this—that so many well-meaning doctors got co-opted. The level of influence is just mind-boggling."[34]

85. In addition to marketing material, the Opioid Manufacturers promoted the use of opioids for chronic pain through "detailers" – sales representatives who visited individual doctors and medical staff in their offices. The Opioid Manufacturers spent massive amounts to have detailers pitch opioids to physicians. In 2014 alone, the Opioid Manufacturers spent in excess of $168 million detailing branded opioids to doctors.

86. The Opioid Manufacturers' detailing to doctors has been effective. Numerous studies indicate that marketing affects prescribing habits, with face-to-face detailing having the greatest influence. Opioid Manufacturers use uniform sales material and train their salespeople – at training seminars and using Powerpoint presentations – to parrot the company's branded messaging.

[33] Patrick Radden Keefe, The Family That Built an Empire of Pain, The New Yorker (Oct. 30. 2017), http://bit.ly/2yHrgvM.
[34] *Id.*

87. Opioid Manufacturers have been reprimanded for their deceptive detailing messages. In March 2010, for example, the FDA found that Actavis had been distributing promotional materials that "minimized the risks associated with Kadian and misleadingly suggested that Kadian is safer than has been demonstrated." Those materials in particular "fail to reveal warnings regarding potentially fatal abuse of opioids, use by individuals other than the patient for whom the drug was prescribed."[35]

88. Purdue was another major culprit in fraudulent detailing. In its training materials, "Purdue instructed sales representatives to assure doctors—repeatedly and without evidence—that 'fewer than one per cent' of patients who took OxyContin became addicted," even though a 1999 Purdue-funded study of patients who used OxyContin for headaches found that "the addiction rate was thirteen per cent."[36]

2. Indirect Marketing

89. The Opioid Manufacturers indirectly marketed their respective branded opioids via unbranded advertising, paid speakers and "key opinion leaders," and industry-funded organizations posing as neutral and credible professional societies and patient advocacy groups (referred to hereinafter as "Front Groups").

90. The Opioid Manufacturers marketed through third-party, unbranded advertising to avoid regulatory scrutiny because that advertising is not submitted to and is normally not reviewed by the FDA. The Opioid Manufacturers also used third-party, unbranded advertising to create the misconception that the false and deceptive messages came from independent and objective sources, rather than from the Opioid Manufacturers.

[35] Letter from Thomas Abrams, Dir., Div. of Drug Mktg., Advert., & Commc'ns, U.S. Food & Drug Admin., to Doug Boothe, CEO, Actavis Elizabeth LLC (Feb. 18, 2010), http://www.fdanews.com/ext/resources/files/archives/a/ActavisElizabethLLC.pdf.
[36] *Id.*

91. Some Opioid Manufacturers could *only* market through indirect means because they had entered into consent decrees that prohibited them from engaging in direct marketing. For example, a 2007 lawsuit against Purdue, brought by multiple States for Purdue's deceptive marketing and promotion of OxyContin, ended in a series of consent decrees restricting the tactics Purdue could use in its direct marketing of OxyContin in the future. To circumvent these restrictions, Purdue simply funneled its energies and funds into indirect marketing.

92. Like the tobacco companies before them, the Opioid Manufacturers used third parties that they funded, directed, and controlled to carry out and conceal their scheme to deceive doctors and patients about the risks and benefits of long-term opioid use for chronic pain.

a. Key Opinion Leaders

93. The concept of a "key opinion leader" was coined by sociologist Paul Lazarsfeld.[37] For Lazarsfeld and his progeny, a key opinion leader is someone held in high regard by those who accept his or her opinions. A key opinion leader might be a celebrity, politician, or doctor. In Lazardfeld's model, new ideas or products spread in a two-step process. A key opinion leader endorses or adopts the idea or product, and then others who hold the key opinion leader in high esteem follow suit.

94. In the 1950s, when studies definitively linked cigarettes to lung cancer, the tobacco industry paid key opinion leaders to say that smoking was still safe.[38] Big Tobacco "co-opted scientists … to the extent of being able to influence peer-reviewed scientific literature."[39]

95. The Opioid Manufacturers took a page from Big Tobacco's playbook, and "recruited their own traveling spokespeople, a group of opioid-pushing Pied Pipers known as

[37] Sergio Sismondo, Ph.D., Key Opinion Leaders and the Corruption of Medical Knowledge: What the Sunshine Act Will and Won't Cast Light on, 41 J.L. Med. & Ethics 635, 636 (2013).
[38] Loddenkemper R, Kreuter M (eds), The Tobacco Epidemic, ed 2, rev. and ext. Prog. Respir Res. Basel, Karger, 2015, vol 42, pp. 14, *available at* http://bit.ly/2BKwB5x.
[39] *Id.*

[key opinion leaders].”[40] The Opioid Manufacturers made “large payments” to these physicians, “primarily intended … to purchase their influence on other physicians.”[41] For example, one influential key opinion leader doctor was dubbed – due to his efforts advocating for wider opioid use – “The King of Pain” by Time magazine.[42] This individual was “on the payroll” of at least four different Opioid Manufacturers.[43]

96. The Opioid Manufacturers used their key opinion leaders to control the message about opioids conveyed in scientific literature, treatment guidelines, and continuing medical education programs, including medical conferences and seminars. For example, “Purdue had a speakers’ bureau, and it paid several thousand clinicians to attend medical conferences [to] deliver presentations about the merits of” its opioid drug, OxyContin.[44] Paying these key opinion leaders to speak at conferences was “worth the investment” because “internal Purdue records indicate that doctors who attended these seminars … wrote OxyContin prescriptions more than twice as often as those who didn’t.”[45] To convince these doctors of the drug’s safety, Purdue used studies that it had bought and paid for. The *New Yorker* says, “The marketing of OxyContin relied on an empirical circularity: [Purdue] convinced doctors of the drug’s safety with literature that had been produced by doctors who were paid, or funded, by the company.”[46]

97. Two prominent opioid advocates paid handsomely by the Opioid Manufacturers were Dr. Russell Portenoy and Dr. Lynn Webster.

Dr. Russell Portenoy

[40] Larry McShane, How Big Tobacco-style marketing propels U.S. opioid crisis — and powers $400B pharma industry, N.Y. Daily News (June 24, 2017), http://nydn.us/2sNRbND.
[41] Sismondo, *supra* note 37, at 635-36.
[42] McShane, *supra* note 40.
[43] *Id.*
[44] Patrick Radden Keefe, The Family That Built an Empire of Pain, The New Yorker (Oct. 30. 2017), http://bit.ly/2yHrgvM.
[45] *Id.*
[46] *Id.*

98. Dr. Russell Portenoy, a doctor at Beth Israel Medical Center in New York, was paid as a "consultant" by Cephalon and Purdue and received substantial speaking fees and research funding from Endo, Janssen, and Mallinckrodt (among others). The *NY Daily News* says that Dr. Portenoy "became a tireless shill" for the opioid industry.[47]

99. Portenoy was instrumental in spreading the falsehood that opioids were safe and effective for chronic pain. In 1986, he wrote a "seminal paper arguing that opioids could be used" not only in "cancer patients with terrible pain," but also in chronic-pain sufferers, such as those with arthritis.[48] Dr. Portenoy claimed that a patient with "knee and hip pain from arthritis" could be given opioids with "very, very low risk" of addiction.[49] Dr. Portenoy based his paper on a study he conducted on patients who were prescribed an opioid for chronic pain. The study looked at only 38 patients, many of whom were prescribed methadone, a milder opioid also used to *treat* heroin addiction.[50]

100. Dr. Portenoy frequently made media appearances to promote opioids, touting the claim that "the likelihood that the treatment of pain using an opioid drug … will lead to addiction is extremely low." He appeared on Good Morning America in 2010 to discuss the use of opioids to treat chronic pain and asserted: "Addiction, when treating pain, is distinctly uncommon."

101. Dr. Portenoy was chiefly responsible for the widespread falsehood that "less than 1%" of opioid users ever become addicted.[51] Dr. Portenoy repeatedly cited a "study" by Dr.

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[47] McShane, *supra* note 40.
[48] Thomas Catan and Evan Perez, A Pain-Drug Champion Has Second Thoughts, Wall Street Journal (Dec. 17, 2012), http://on.wsj.com/2p9B2nI.
[49] Assuming the patient has no personal or family history of substance abuse or mental illness, Health.com, Dr. Russell Portenoy, a Leader in Pain Medicine, Answers Critical Questions About Using Opioids for Chronic Pain (Mar. 17, 2017), http://www.health.com/health/condition-article/0,,20189630,00.html.
[50] *See* Portenoy RK and Foley KM, Chronic use of opioid analgesics in non-malignant pain, Pain, 1986 May;25(2):171-86, *available at* https://www.ncbi.nlm.nih.gov/pubmed/2873550.
[51] Harrison Jacobs, This one-paragraph letter may have launched the opioid epidemic, Business Insider (May 26, 2016), http://read.bi/2BPnXmb.

Hershel Jick,[52] even though the study was merely a five-sentence letter-to-the-editor published in a medical journal in 1980.[53] Although Portenoy claimed that Dr. Jick's analysis showed that opioids were safe for long-term use, "Jick's analysis proved no such thing. The "study" analyzed a database of hospitalized patients at Boston University Medical Center who were given small doses of opioids in a controlled [inpatient] setting to ease suffering from acute pain. These patients were not given long-term opioid prescriptions, which they'd be free to administer at home."[54] Although the "study" had nothing to do with long-term use outside the confines of a hospital, Portenoy asserted that the Jick analysis proved that opioids were safe for long-term use.

102. Portenoy took steps to ensure that his 1% statistic would be widely publicized and cited. In the 1990s, he pushed this statistic during his lectures and through the American Pain Society, of which he was president.[55] Citing his 1% statistic, "Dr. Portenoy helped write a landmark 1996 consensus statement by two professional pain societies that said there was little risk of addiction or overdose among pain patients."[56] As a result of Dr. Portenoy's efforts, the Jick analysis has been cited in 901 academic publications.[57] A 1990 article in Scientific American cited the Jick analysis as an "extensive study."[58] A 2001 Time magazine article said it was a "landmark study" that proved that the "exaggerated fear that patients would become addicted" to opioids was "basically unwarranted."[59]

103. Portenoy's 1% statistic from the Jick letter was one of the "primary justifications" that doctors used for more liberally prescribing opioids starting in the early 1990s.[60] When

[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] Catan, *supra* note 48.
[56] *Id.*
[57] Jacobs, *supra* note 51.
[58] *Id.*
[59] *Id.*
[60] *Id.*

investigative journalist Sam Quinones dug into the causes of the opioid crisis, including interviewing doctors and other medical professionals, the "Jick letter was referenced repeatedly to justify the increase in liberal prescriptions of opioid painkillers."[61] "Over time, the … Jick letter, and its claim that 'less than 1%' of opioid users became addicted, became 'gospel' for medical professionals, Dr. Marsha Stanton told Quinones."[62] Dr. Stanton continued, "I used [the Jick letter] in lectures all the time. Everybody did. It didn't matter whether you were a physician, a pharmacist, or a nurse; you used it. No one disputed it. Should we have? Of course we should have."[63]

104. "Today, even proponents of opioid use say that figure was wrong," says the *Wall Street Journal*. One opioid advocate said, "It's obviously crazy to think that only 1% of the population is at risk for opioid addiction." Modern studies put the rate much higher. A 2015 meta-study found that up to 29% of chronic-pain patients started abusing opioids, and up to 12% became addicted during the study period.[64]

105. In recent years, Dr. Portenoy reversed his position on the safety of opioids.[65] In a 2011 interview, "Portenoy admitted that he used the … Jick letter, along with other similar studies on opioid use, to encourage more liberal prescribing of opioids."[66] Portenoy admitted, "None of [those studies] represented real evidence, and yet what I was trying to do was to create a narrative so that the primary care audience would look at this information and feel more comfort about opioids in a way they hadn't before. In essence this was education to destigmatize

[61] *Id.*
[62] *Id.*
[63] *Id.*
[64] Vowles et al., Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis, Pain (Apr. 2015), *available at* https://www.ncbi.nlm.nih.gov/pubmed/25785523.
[65] Catan, *supra* note 48.
[66] Jacobs, *supra* note 51.

[opioids] … and because the primary goal was to destigmatize, we often left evidence behind."[67] Portenoy now admits that he "gave innumerable lectures in the late 1980s and '90s about addiction that weren't true."[68] These lectures falsely claimed that less than 1% of patients would become addicted to opioids. Portenoy candidly stated: "Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? . . . I guess I did."[69] Portenoy says it's "quite scary" to think about how he "contributed to soaring rates of addiction and overdose deaths."[70] Portenoy said that his opioid advocacy "was clearly the wrong thing to do."[71]

Dr. Lynn Webster

106. Another key opinion leader paid by the opioid industry was Dr. Lynn Webster, Chief Medical Director of Lifetree Clinical Research, an otherwise unknown pain clinic in Salt Lake City, Utah. Dr. Webster was President of the American Academy of Pain Medicine in 2013. Dr. Webster was the author of numerous continuing medical education courses sponsored by Cephalon, Endo, and Purdue. He received significant funding from the Opioid Manufacturers, including nearly $2 million from Cephalon.

107. During a portion of his time as a key opinion leader, Dr. Webster was under investigation by the Drug Enforcement Administration (DEA) for overprescribing opioids. The DEA raided his clinic in 2010. More than twenty of Dr. Webster's former patients have died of opioid overdoses.

[67] *Id.*
[68] *Id.*
[69] *Id.*
[70] *Id.*
[71] *Id.*

108. Dr. Webster created and promoted an Opioid Risk Tool,[72] a five question, one-minute screening tool that purportedly allows doctors to pre-screen patients for addiction risk factors. Dr. Webster claimed the tool could identify patients likely to become addicted, so doctors could avoid prescribing opioids to these patients. The Tool is supposed to give doctors confidence in prescribing opioids to individuals that the Tool identifies as low risk. The Tool has been touted by a variety of industry-supported publications, and appears or is linked to on websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue entitled "Managing Patient's Opioid Use: Balancing the Need and the Risk." Dr. Webster recommended use of his Opioid Risk Tool to prevent "overuse of prescriptions" and "overdose deaths." This webinar was available to and was intended to reach doctors in Puerto Rico.[73]

109. The Tool is inaccurate. It correctly identifies individuals with heightened risk of opioid addiction only 45% of the time—worse than a coin flip.[74] Clinical interviews with patients and more robust screening tools are 1.71 and 1.62 times more accurate, respectively.[75]

110. Unaware of the flawed science and industry bias behind the tool, certain states and public entities have incorporated the Opioid Risk Tool into their own opioid guidelines, relying on representations about its accuracy made by the Opioid Manufacturers and their paid key opinion leaders.

111. Dr. Webster also popularized the perplexing concept of "pseudoaddiction," the notion that addictive behaviors should be seen not as warnings, but as indications of undertreated

[72] https://www.drugabuse.gov/sites/default/files/files/OpioidRiskTool.pdf.
[73] *See* Emerging Solutions in Pain, Managing Patient's Opioid Use: Balancing the Need and the Risk, http://bit.ly/2zeYZtK (last visited Aug. 22, 2017).
[74] Rene Claxton, MD, and Robert Arnold, MD, Screening for Opioid Misuse and Abuse, Palliative Care Network of Wisconsin, http://bit.ly/2kVfwh6 (noting that the Opioid Risk Tool has a "sensitivity" of 45%). Sensitivity is a measure of the true positive rate of a diagnostic test (i.e., the opposite of the rate of false positives).
[75] *Id*. (Clinical interviews have a sensitivity of 77% and the Screener and Opioid Assessment of Pain Patients (SOAPP), a 14-question screening tool, had a sensitivity of 73%).

pain. In Dr. Webster's description, the only way to differentiate the two is to increase a patient's dose of opioids. He and co-author Beth Dove wrote in their 2007 publication *Avoiding Opioid Abuse While Managing Pain* that when a doctor sees signs of aberrant behavior in a patient, increasing their opioid dose "in most cases . . . should be the clinician's first response."[76] Endo distributed this publication to doctors. Years later, Dr. Webster reversed himself, acknowledging that "[pseudoaddiction] obviously became too much of an excuse to give patients more medication."[77]

112. Pro-opioid key opinion leaders, like Dr. Portenoy and Dr. Webster, are one of the most important avenues that the Opioid Manufacturers used to spread their false and deceptive statements about the risks and benefits of long-term opioid use. The Opioid Manufacturers knew that doctors rely heavily and less critically on their peers for guidance, and key opinion leaders provide the false appearance of unbiased and reliable support for use of opioids to treat chronic pain.

b. Front Groups

113. The Opioid Manufacturers also entered into arrangements with seemingly unbiased and independent patient and professional organizations to promote opioids for the treatment of chronic pain. Under the direction and control of the Opioid Manufacturers, these "Front Groups" generated treatment guidelines, unbranded materials, and programs that promoted chronic opioid therapy. As the Tobacco Institute did for the tobacco industry, these Front Groups assisted the Opioid Manufacturers by responding to negative articles, advocating against regulatory changes that would limit opioid prescribing in accordance with the scientific

[76] Lynn Webster & Beth Dove, Avoiding Opioid Abuse While Managing Pain (2007).
[77] John Fauber, Painkiller Boom Fueled by Networking, Milwaukee Wisc. J. Sentinel, Feb. 18, 2012, http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by- networking-dp3p2rn-139609053.html.

evidence, and conducting outreach to vulnerable patient populations who Opioid Manufacturers wanted to target.

114. These Front Groups depended on the Opioid Manufacturers for funding and, in some cases, for survival. The Opioid Manufacturers also controlled the programs and materials put out by these groups by collaborating on, editing, and approving their content, and by funding their dissemination. In doing so, the Opioid Manufacturers made sure that the Front Groups would generate only the messages that the Opioid Manufacturers wanted to distribute. Despite this, the Front Groups held themselves out as independent and serving the needs of their members – whether patients suffering from pain or doctors treating those patients.

115. The Opioid Manufacturers utilized many different Front Groups. Several of the most prominent are described below, but there are many others.

American Pain Foundation

116. The most prominent of the Opioid Manufacturers' Front Groups was the American Pain Foundation, which received more than $10 million in funding from the Opioid Manufacturers, primarily Endo and Purdue, from 2007 until it closed its doors in May 2012. The American Pain Foundation issued education guides for patients, reporters, and policymakers that touted the benefits of opioids for chronic pain and trivialized their risks, particularly the risk of addiction. American Pain Foundation also launched a campaign to promote opioids for returning veterans, which has contributed to high rates of addiction and other adverse outcomes – including death – among returning soldiers. American Pain Foundation also engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their "right" to pain treatment, namely opioids. All of the programs and materials were available nationally and were intended to reach citizens of the Commonwealth.

117. In 2009 and 2010, more than 80% of American Pain Foundation's operating budget came from pharmaceutical industry sources.[78] By 2011, American Pain Foundation was entirely dependent on incoming grants from Purdue, Cephalon, Endo, and other Opioid Manufacturers to avoid going into debt.

118. American Pain Foundation held itself out as an independent patient advocacy organization. It often engaged in grassroots lobbying against various legislative initiatives that might limit opioid prescribing, and thus the profitability of its sponsors. It was often called upon to provide "patient representatives" for the Opioid Manufacturers' promotional activities, including for Janssen's Let's Talk Pain and Purdue's Partners Against Pain initiatives. Janssen's Let's Talk Pain initiative was a coalition of three Front Groups and Janssen that used

[78] Including industry grants for specific projects, American Pain Foundation received about $2.3 million from industry sources out of total income of about $2.85 million in 2009; its budget for 2010 projected receipts of roughly $2.9 million from drug companies, out of total income of about $3.5 million.

patient stories and testimonials to convince doctors and other patients that there was need for more liberal prescribing of opioids for pain.[79] Let's Talk Pain's catch-phrase acknowledged that non-pain suffers might have doubts about the need for prescribing opioids: "To hear about pain is to have doubt; to experience pain is to have certainty."[80] Similarly, Purdue's Partners Against Pain initiative used literature and audiotapes aimed at physicians and videos aimed at patients to claim that OxyContin changed lives, and "that the risk of addiction from OxyContin was extremely small."[81]

119. Although American Pain Foundation fronted as a patient advocacy group, American Pain Foundation functioned largely as an advocate for the interests of the Opioid Manufacturers, not patients.

120. On several occasions, representatives of the Opioid Manufacturers, often at informal meetings at conferences, suggested activities and publications for American Pain Foundation to pursue. American Pain Foundation then submitted grant proposals seeking funding for these activities, knowing that the drug companies would support the proposed initiatives or publication projects.

121. The U.S. Senate Finance Committee began looking into American Pain Foundation in May 2012 to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. The investigation caused considerable damage to American Pain Foundation's credibility as an objective and neutral third party, and the Opioid Manufacturers stopped funding it. Within days of being targeted by the Senate investigation, American Pain Foundation's board voted to dissolve the organization "due to

[79] *See* Partners Against Pain (Nov. 26, 2011), http://bit.ly/2pchqPP.
[80] *Id*.
[81] Art Van Zee, MD, The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy, Am J Public Health. 2009 February; 99(2): 221–227, *available at* http://bit.ly/2DyLMPs.

irreparable economic circumstances." American Pain Foundation "cease[d] to exist, effective immediately."[82]

American Academy of Pain Medicine

122. Another front group for the Opioid Manufacturers was the American Academy of Pain Medicine. With the assistance, prompting, involvement, and funding of the Opioid Manufacturers, the American Academy of Pain Medicine issued purported treatment guidelines and sponsored and hosted medical education programs essential to the Opioid Manufacturers' deceptive marketing of chronic opioid therapy.

123. American Academy of Pain Medicine received substantial funding from opioid manufacturers. For example, American Academy of Pain Medicine maintained a corporate relations council, membership on which cost a substantial sum. The benefits of membership included allowing Opioid Manufacturer employees to present educational programs at off-site dinner symposia in connection with American Academy of Pain Medicine's marquee event – its annual meeting typically held in Palm Springs, California. American Academy of Pain Medicine describes the annual event as an "exclusive venue" for offering education programs to doctors. Membership in the corporate relations council also allowed drug company executives and marketing staff to meet with American Academy of Pain Medicine executive committee members in small settings. Defendants Endo, Purdue, and Cephalon—and Mallinckrodt's then-parent, Covidien pllc—were members of the council and presented deceptive programs to doctors who attended this annual event. Endo not only attended American Academy of Pain Medicine conferences, but also funded its continuing medical education programs and distributed its publications.

[82] Charles Ornstein & Tracy Weber, Senate Panel Investigates Drug Companies' Ties to Pain Groups, Wash. Post, May 8, 2012, https://www.washingtonpost.com/national/health-science/senate-panel-investigates-drug-companies-ties-to-pain groups/2012/05/08/ gIQA2X4qBU_ story.html.

124. American Academy of Pain Medicine's conferences heavily emphasized sessions on opioids, rather than other pain management options. At one conference alone, 37 out of roughly 40 sessions were on opioids. American Academy of Pain Medicine's presidents have included top industry-supported key opinion leaders like Dr. Perry Fine and Lynn Webster. Dr. Webster was even elected president of American Academy of Pain Medicine while under a DEA investigation for overprescribing opioids to his patients.

125. The Opioid Manufacturers were able to influence American Academy of Pain Medicine through their membership on its council, their significant and regular funding, and the election of pro-opioid key opinion leaders to top leadership positions within the organization.

126. In 1996, American Academy of Pain Medicine and the American Pain Society, another front group, jointly issued a consensus statement, "The Use of Opioids for the Treatment of Chronic Pain," which endorsed opioids to treat chronic pain and claimed that the risk of a patient's addiction to opioids was low. Dr. David Haddox, who co-authored the American Academy of Pain Medicine/American Pain Society statement, was a paid speaker for Purdue at the time (and currently serves as a vice president at Perdue). The other co-author, Dr. Portenoy, was a paid consultant for Purdue and Cephalon. The consensus statement remained on American Academy of Pain Medicine's website until 2011, when a doctor complained that it had been debunked, and it was taken down.[83]

127. American Academy of Pain Medicine and American Pain Society issued their own guidelines in 2009 and continued to recommend the use of opioids to treat chronic pain.[84]

[83] The Use of Opioids for the Treatment of Chronic Pain: A Consensus Statement From the American Academy of Pain Medicine and the American Pain Society, 13 Clinical J. Pain 6 (1997).
[84] Roger Chou et al., Clinical Guidelines for the Use of Chronic Opioid Therapy in Chronic Non-Cancer Pain, 10 J. Pain 113 (2009).

128. Treatment guidelines are widely relied upon by doctors, especially the general practitioners and family doctors targeted by the Opioid Manufacturers. Treatment guidelines not only directly inform doctors' prescribing practices, but are cited throughout the scientific literature and referenced by third-party payers in determining whether they should cover treatments for specific indications. Pharmaceutical sales representatives employed by Endo, Actavis, and Purdue discuss treatment guidelines with doctors during individual sales visits.

129. At least fourteen of the 21 panel members who drafted the American Academy of Pain Medicine/American Pain Society guidelines, including key opinion leaders Dr. Portenoy and Dr. Perry Fine of the University of Utah, received support from Janssen, Cephalon, Endo, and Purdue. The 2009 guidelines promoted opioids as "safe and effective" for treating chronic pain, despite acknowledging limited evidence, and concluded that the risk of addiction is manageable for patients regardless of past abuse histories.[85] One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the 2009 guidelines were influenced by contributions that drug companies, including Opioid Manufacturers, made to the sponsoring organizations and committee members.

130. The 2009 American Academy of Pain Medicine/American Pain Society guidelines have been a particularly effective channel of deception and have not only influenced treating physicians, but also manipulated the body of scientific evidence on opioids; the guidelines have been cited hundreds of times in academic literature, were disseminated in the Commonwealth during the relevant time period, are still available online, and were reprinted in the Journal of Pain. The Opioid Manufacturers widely referenced and promoted the 2009

[85] *Id.*

guidelines without disclosing the lack of evidence to support them or the Opioid Manufacturers' financial support to members of the panel.

131. The Opioid Manufacturers worked together, through Front Groups, to spread their deceptive messages about the risks and benefits of long-term opioid therapy. For example, They combined their efforts through the Pain Care Forum, which began in 2004 as an American Pain Foundation project. Pain Care Forum is comprised of representatives from opioid manufacturers (including Cephalon, Endo, Janssen, and Purdue) and various Front Groups, almost all of which received substantial funding from the Opioid Manufacturers. Among other projects, Pain Care Forum worked to ensure that an FDA-mandated physician education project on opioids was not overly negative and did not have mandatory participation, which the Opioid Manufacturers determined would reduce opioid prescribing.

132. The above-described Front Groups were some of the most prominent, but other groups utilized by the Opioid Manufacturers include: the American Geriatrics Society, the Federation of State Medical Boards, American Chronic Pain Association, the Center for Practical Bioethics, the U.S. Pain Foundation, and the Pain & Policy Studies Group.

C. Opioid Manufacturers' Specific Misconduct and Misrepresentations, Which Created The Opioid Epidemic.

133. The Opioid Manufacturers embarked upon a campaign of false and deceptive assurances grossly understating and misstating the dangerous addiction risks of their opioid drugs, while exaggerating the benefits of opioids for those suffering from chronic pain.

134. Using both direct and indirect marketing to convince physicians and patients that opioids were safe, the Opioid Manufacturers trivialized the risks of long-term opioid use, particularly the risk of addiction, through a series of misrepresentations that have been debunked by the FDA and CDC. These misrepresentations reinforced each other and created the

dangerously misleading impression that opioid addiction was rare, preventable, or easily managed.

1. Misrepresentation: Low Risk of Addiction

135. The Opioid Manufacturers expended significant funds to foster the belief among doctors and patients that opioids were low risk because most patients would not become addicted, or because those at greatest risk for addiction could be identified and managed.

136. Purdue created a promotional video in 1998 called "I got my life back," featuring seven patients whose chronic pain was alleviated when they started taking OxyContin. The video took its title from a quote by one of the patients, Johnny Sullivan, who said that he "got his life back" and was able to return to work by taking OxyContin.[86] Purdue distributed the video to 15,000 doctors across the country.[87]

137. Two years later, Purdue produced and distributed a follow-up video, "I got my life back – Part II," featuring six of the previous patients, saying they were still doing well.[88] The video also featured clips of North Carolina pain specialist Dr. Alan Spanos, reassuring other physicians that opioids were safe and effective.[89] Spanos was on Purdue's payroll at the time as a paid speaker.[90] In the video, Spanos says, "We doctors were wrong in thinking that opioids can't be used long term. They can be and they should be. We used to think they'd stop working, or the patients would become addicts …These six cases show how wrong those views were."[91] Spanos reiterates again, at the end of the video, "What did we learn from these six patients? Most

[86] Physicians for Responsible Opioid Prescribing, OxyContin Poster Children 15 Years Later (Sept. 9, 2012), http://bit.ly/2phvsQa.
[87] *Id*
[88] *Id.*
[89] *Id.*
[90] John Fauber and Ellen Gabler, What happened to the poster children of OxyContin?, Milwaukee Journal-Sentinel (Sept. 8, 2012), http://bit.ly/2kNdmkp.
[91] Physicians for Responsible Opioid Prescribing, *supra* note 86.

importantly, they refute the myth that long-term opioid use would inevitably lead to addiction . . . ."[92]

138. But, for Johnny Sullivan, who inspired the video's title, OxyContin did not turn out to be the "wonder drug" that Purdue promoted it as.[93] Fifteen years after the original video was filmed, Physicians for Responsible Opioid Prescribing followed up with Johnny's widow, Mary Lou Sullivan. She said, "When Johnny first started taking OxyContin, he actually thought he felt pretty good."[94] But, Johnny soon became addicted to OxyContin, and as he built a tolerance to the drug, he had to start taking larger and larger doses. Ms. Sullivan says, "When he was on high doses of pain medicine, it was just like night and day. It was like a part of him was gone. It got to the point where I hated to even go out to eat with him because he would fall asleep right in the middle of eating. People would be looking and wondering: what in the world is wrong with him."[95] Johnny started experienced extreme drowsiness, a common side effect of opioids.

139. Ms. Sullivan says that OxyContin was so powerful that Johnny couldn't control his addiction. She says, "Yes, Johnny had chronic pain, but he was also highly addicted to the medicine. The medicine was overpowering him. I mean, he was losing control."[96] He twice overdosed, and had to go to the emergency room.[97]

140. Things only got worse from there. Ms. Sullivan continued, "He came home one day and his whole windshield was busted. His mirror was knocked off the side. He fell asleep; he hit a mailbox; he knocked a mirror off. Two or three times that happened where he fell asleep

[92] *Id.*
[93] *Id.*
[94] *Id.*
[95] *Id.*
[96] *Id.*
[97] *Id.*

driving."[98] But, he was too addicted to ever stop taking the medication. "I told my sons one day, I said, 'That medicine is going to kill him.'"[99] Ms. Sullivan continues, "He might have said he got his life back, but it took his life in the end."[100] Johnny fell asleep at the wheel and was killed in a car wreck on March 2, 2008 – ten years after making the original "I got my life back" video.

141. The original video also featured a back-pain patient, Lauren Cambra, discussed above in Section (B)(1). Ms. Cambra also got addicted to OxyContin, and as her body built up a tolerance, she had to start taking stronger and stronger doses. Ms. Cambra says, "Your body gets used to it, so we got it increased. We got it increased again; and we got it increased again."[101] After her repeated dosage increases, she was so doped up on the drug that she could hardly move. She explains, "You couldn't have gotten me to go out in the yard and play with my grandkids. I didn't do it."[102] After she lost her house, car, job, and health insurance, she quit taking OxyContin – not by choice, but because she couldn't afford it anymore.[103] It took her six to eight months before the extreme cravings stopped. When asked if she would ever take OxyContin again, she said absolutely not: "It's a synthetic heroin. I mean, good God – who would just knowingly want to just addict themselves to heroin."[104]

142. In addition, Actavis's predecessor distributed a patient education brochure, *Managing Chronic Back Pain*, beginning in 2003 that falsely claimed opioid addiction is "less likely if you have never had an addiction problem." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, it appears that Actavis continued to use this brochure in 2009 and beyond.

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[98] *Id.*
[99] *Id.*
[100] *Id.*
[101] *Id.*
[102] *Id.*
[103] *Id.*
[104] *Id.*

143. Cephalon and Purdue sponsored the American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which suggested that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining duplicative opioid prescriptions from multiple sources, or theft.[105]

144. Endo sponsored a website, "PainKnowledge," which claimed in 2009 that "[p]eople who take opioids as prescribed usually do not become addicted." Another Endo website, PainAction.com, stated "Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them." Endo also distributed an "Informed Consent" document on PainAction.com that misleadingly suggested that only people who "have problems with substance abuse and addiction" are likely to become addicted to opioid medications.

145. Endo distributed a pamphlet with the Endo logo entitled *Living with Someone with Chronic Pain*, which stated that: "Most health care providers who treat people with pain agree that most people do not develop an addiction problem."

146. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which described as "myth" the claim that opioids are addictive, and asserted as fact that "[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain."

147. Janssen runs a website, Prescriberesponsibly.com[106] that claims that concerns about opioid addiction are "overestimated."

148. Purdue sponsored American Pain Foundation's *A Policymaker's Guide to Understanding Pain & Its Management*, which claims that less than 1% of children prescribed

[105] Am. Pain Found., Treatment Options: A Guide for People Living in Pain (2007) [hereinafter American Pain Foundation, Treatment Options], https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf.
[106] http://www.prescriberesponsibly.com/

opioids will become addicted and that pain is undertreated due to "[m]isconceptions about opioid addiction."[107]

149. In 2010, Mallinckrodt sponsored an initiative, Collaborating and Acting Responsibly to Ensure Safety (C.A.R.E.S.), through which it published and promoted the book "Defeat Chronic Pain Now!" aimed at chronic pain patients. The book, which remains available for purchase and is promoted online at www.defeatchronicpainnow.com, advises those considering whether to take opioid drugs that "[o]nly rarely does opioid medication cause a true addiction."[108] Further, the book advises that even the issue of tolerance is "overblown," because "[o]nly a minority of chronic pain patients who are taking long-term opioids develop tolerance." In response to a hypothetical question from a chronic back pain patient who expresses a fear of becoming addicted, the book advises that "[i]t is very uncommon for a person with chronic pain to become 'addicted' to narcotics IF (1) he doesn't have a prior history of any addiction and (2) he only takes the medication to treat pain."

150. These claims are contrary to longstanding scientific evidence. A meta-analysis of 38 previously-performed studies concluded that on average, the studies found that 21% to 29% of patients will start abusing opioids, and another 8 to 12% will become addicted.[109] A Perdue-funded study in 1999 found that 13% of OxyContin users became addicted.

151. The State of New York, in a 2016 settlement agreement with Endo, found that opioid "use disorders appear to be highly prevalent in chronic pain patients treated with opioids, with up to 40% of chronic pain patients treated in specialty and primary care outpatient centers

[107] Am. Pain Found., A Policymaker's Guide to Understanding Pain and Its Management 6 (2011) [hereinafter American Pain Foundation, Policymaker's Guide], http://s3.documentcloud.org/documents/277603/apf-policymakers-guide.pdf.
[108] Charles E. Argoff & Bradley S. Galer, Defeat Chronic Pain Now! (2010).
[109] Vowles, *supra* note 64.

meeting the clinical criteria for [opioid addiction]."[110] Endo had claimed on its www.opana.com website that "[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted," but the State of New York found that Endo had no evidence for that statement. Consistent with this, Endo agreed not to "make statements that . . . opioids generally are non- addictive" or "that most patients who take opioids do not become addicted" in New York. Endo remains free, however, to make those statements in this Commonwealth.

152. The CDC has issued guidelines for prescribing opioids that note that there is "[e]xtensive evidence" that opioids are addictive.[111]

153. The FDA has stated that: because of the "known serious risks" associated with long-term opioid use, including "risks of addiction, abuse, and misuse, even at recommended doses, and because of the greater risks of overdose and death," opioids should be used only "in patients for whom alternative treatment options" like non-opioid drugs have failed.[112]

2. Misrepresentation: Pseudoaddiction

154. In addition to mischaracterizing the highly addictive nature of the drugs they were pushing, the Opioid Manufacturers also fostered a fundamental misunderstanding of the signs of addiction. Specifically, the Opioid Manufacturers misrepresented, to doctors and patients, that warning signs and symptoms of addiction were, instead, signs of undertreated pain (*i.e.*,

[110] Assurance of Discontinuance, In re Endo Health Solutions Inc. and Endo Pharm. Inc. (Assurance No. 15-228), at 16, https://ag.ny.gov/pdfs/Endo_AOD_030116-Fully_Executed.pdf.
[111] Deborah Dowell et al., CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016, Morbidity & Mortality Wkly. Rep., Mar. 18, 2016, at 15 [hereinafter 2016 CDC Guideline], https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.
[112] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Andrew Koldny, M.D., President, Physicians for Responsible Opioid Prescribing (Sept. 10, 2013), https://www.regulations.gov/contentStreamer?documentId=FDA- 2012-P-0818-0793&attachmentNumber=1&contentType=pdf.; Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Peter R. Mathers & Jennifer A. Davidson, Kleinfeld, Kaplan and Becker, LLP (Mar. 22, 2016), https://www.regulations.gov/contentStreamer?documentId=FDA-2014-P-0205-0006&attachmentNumber=1&contentType=pdf.

pseudoaddiction), and instructed doctors to increase the opioid prescription dose for patients who were already in danger.

155. One of Purdue's employees, Dr. David Haddox, invented the concept of "pseudoaddiction," and key opinion leader Dr. Webster popularized the term.

156. Cephalon and Purdue sponsored *Responsible Opioid Prescribing* (2007), which taught that behaviors such as "requesting drugs by name," "demanding or manipulative behavior," seeing more than one doctor to obtain opioids, and hoarding are all signs of pseudoaddiction, rather than true addiction.[113] The 2012 edition of *Responsible Opioid Prescribing*, which remains available online, continues to teach that pseudoaddiction is real.[114]

157. Janssen sponsored, funded, and edited the Let's Talk Pain website, which in 2009 stated: "pseudoaddiction . . . refers to patient behaviors that may occur when pain is under-treated . . . . Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management."

158. Endo sponsored a National Initiative on Pain Control continuing medical education program in 2009 entitled "Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia," which promoted pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain. Endo appears to have substantially controlled National Initiative on Pain Control by funding National Initiative on Pain Control projects; developing, specifying, and reviewing content; and distributing National Initiative on Pain Control materials.

159. Purdue published a pamphlet in 2011 entitled *Providing Relief, Preventing Abuse*, which described pseudoaddiction as a concept that "emerged in the literature" to describe the

[113] Scott M. Fishman, M.D., Responsible Opioid Prescribing: A Physician's Guide (2007) at 62.
[114] *See* Scott M. Fishman, M.D., Responsible Opioid Prescribing: A Physician's Guide (2d ed. 2012).

inaccurate interpretation of [drug-seeking behaviors] in patients who have pain that has not been effectively treated."

160. Purdue sponsored a continuing medical education program titled "Path of the Patient, Managing Chronic Pain in Younger Adults at Risk for Abuse." In a dramatic rendering, a chronic pain patient with a history of drug abuse is depicted telling his doctor that he is taking twice as many hydrocodone pills as directed. The narrator notes that because of pseudoaddiction, the doctor should not assume the patient is addicted even if he persistently asks for a specific drug, seems desperate, hoards medicine, or "overindulges in unapproved escalating doses." The doctor treats this patient by prescribing a high dose, long-acting opioid—the perfect recipe for addiction.

161. Mallinckrodt's "Defeat Chronic Pain Now!" book, which is still available, and is promoted online at www.defeatchronicpainnow.com, teaches laypeople that "pseudoaddiction" is "caused by their doctor not appropriately prescribing the opioid medication." It teaches that "[p]seudoaddiction happens when a patient's opioid medication is not being prescribed in doses strong enough to provide good pain relief, or if the drug is not being prescribed often enough throughout the day. . . When a pseudoaddicted patient is prescribed the proper amount of opioid medication, he or she doesn't take any extra pills because his or her pain is relieved."

162. In its 2016 guidelines on opioid prescribing, the CDC rejects pseudoaddiction as a fictitious invention of the Opioid Manufacturers to push more opioid drugs onto already addicted patients.

3. Misrepresentation: Screening and Risk-Mitigation Tools Are Accurate and Effective in Preventing Opioid Misuse

163. In addition to misstating the addiction risk and inventing the pseudoaddiction falsehood, the Opioid Manufacturers created false guidelines stating that addiction risk screening

tools, patient contracts, and similar strategies allow them to reliably identify and safely prescribe opioids to patients predisposed to addiction. The Opioid Manufacturers' misrepresentations made doctors more comfortable prescribing opioids to their patients, and patients more comfortable starting on opioid therapy for chronic pain.

164. Endo paid for a 2007 supplement in the *Journal of Family Practice* written by a doctor who became a member of Endo's speakers' bureau in 2010. The supplement, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, emphasized the effectiveness of screening tools, claiming that patients at high risk of addiction could safely receive chronic opioid therapy using a "maximally structured approach" involving toxicology screens and pill counts.

165. Purdue sponsored a 2011 webinar, *Managing Patient's Opioid Use: Balancing the Need and Risk*, which claimed that screening tools, urine tests, and patient agreements prevent "overuse of prescriptions" and "overdose deaths."

166. As recently as 2015, Purdue has represented in scientific conferences that "bad apple" patients, and not opioids, are the source of the addiction crisis and that once those "bad apples" are identified, doctors can safely prescribe opioids without causing addiction.

167. The 2016 CDC guidelines on opioid prescribing confirm the falsity of these claims. The guidelines explains that there are no studies assessing the effectiveness of risk mitigation strategies "for improving outcomes related to overdose, addiction, abuse or misuse."

4. Misrepresentation: Opioid Addiction Is Easy to Treat

168. A fourth category of deceptive messaging regarding dangerous opioids is the Opioid Manufacturers' false assurances regarding the alleged ease of eliminating opioid dependence. The Opioid Manufacturers falsely claimed that opioid dependence can easily be addressed by tapering off the medication and that opioid withdrawal is not a problem, but they

failed to disclose that cessation of opioid use becomes more difficult the longer the patient takes the drug.

169. The Opioid Manufacturers also downplayed the severity of opioid detoxification. For example, a continuing medical education sponsored by Endo, entitled *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms can be avoided by tapering a patient's opioid dose by 10%-20% for 10 days. Similarly, in the 2010 Mallinckrodt/C.A.R.E.S. publication "Defeat Chronic Pain Now!," potential opioid users are advised that tolerance to opioids is "easily remedied," and that "[a]ll patients can be safely taken off opioid medication if the dose is slowly tapered down by their doctor."

170. In reality, tapering is not a panacea. Clinical guidelines on *Tapering Opioid Pain Medication* note that opioid-addicted patients have a very high recidivism rate, meaning they often relapse after being tapered off opioids.[115]

5. Misrepresentation: Higher Doses Are Not Higher Risk

171. A fifth category of false and deceptive statements the Opioid Manufacturers made to sell more drugs is that opioid dosages could be increased indefinitely without added risk. The ability to escalate dosages was critical to Defendants' efforts to market opioids for long-term use to treat chronic pain because, absent this misrepresentation, doctors would have abandoned treatment when patients built up tolerance and lower dosages did not provide pain relief. In reality, the higher the opioid dose, the greater the risk of overdose and death.

172. Cephalon and Purdue sponsored American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which claims that some patients "need" a larger dose of an opioid, regardless of the dose currently prescribed. The guide stated that opioids have

[115] Intermountain Healthcare, *Tapering Opioid Pain Medication* (Aug. 2015), http://bit.ly/2lfxUBl.

"no ceiling dose" and insinuated that they are therefore the most appropriate treatment for severe pain.

173. Actavis's predecessor created a patient brochure for Kadian in 2007 that stated, "Over time, your body may become tolerant of your current dose. You may require a dose adjustment to get the right amount of pain relief. This is not addiction." Based on Actavis's acquisition of its predecessor's marketing materials along with the rights to Kadian, Actavis appears to have continued to use these materials in 2009 and beyond.

174. Endo sponsored a website, "PainKnowledge," which claimed in 2009 that opioid dosages may be increased until "you are on the right dose of medication for your pain."

175. Endo distributed a pamphlet edited by a key opinion leader entitled *Understanding Your Pain: Taking Oral Opioid Analgesics* (2004 Endo Pharmaceuticals PM-0120). In Q&A format, it asked "If I take the opioid now, will it work later when I really need it?" The response is, "The dose can be increased. . . . You won't 'run out' of pain relief."[116]

176. Janssen sponsored a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which was distributed by its sales force. This guide listed dosage limitations as "disadvantages" of other pain medicines but omitted any discussion of risks of increased opioid dosages.

177. Purdue, according to its own internal documents, found that doctors had the false understanding that the company's prescription opioid, OxyContin, was "less potent than morphine."[117] It was not. Purdue officials actively exploited this "misperception."[118]

[116] Margo McCaffery & Chris Pasero, Endo Pharm., Understanding Your Pain: Taking Oral Opioid Analgesics (Russell K Portenoy, M.D., ed., 2004).
[117] Keefe, *supra* note 44.
[118] *Id*.

178. Purdue's In the Face of Pain website promoted the notion that if a patient's doctor does not prescribe what, in the patient's view, is a sufficient dosage of opioids, he or she should find another doctor who will.

179. Purdue sponsored American Pain Foundation's *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that dosage escalations are "sometimes necessary," and that "the need for higher doses of medication is not necessarily indicative of addiction," but inaccurately downplayed the risks from high opioid dosages.

180. In 2007, Purdue sponsored a continuing medical education entitled "Overview of Management Options" that was available for continuing medical education credit and available until at least 2012. The continuing medical education was edited by a key opinion leader and taught that NSAIDs and other drugs, but not opioids, are unsafe at high dosages.

181. Purdue presented a 2015 paper at the College on the Problems of Drug Dependence, "the oldest and largest organization in the US dedicated to advancing a scientific approach to substance use and addictive disorders," challenging the correlation between opioid dosage and overdose.[119]

182. In the 2010 Mallinckrodt/C.A.R.E.S. publication "Defeat Chronic Pain Now!" potential opioid users are warned about of the risk of "[p]seudoaddiction [b]ecause of a [l]ow [d]ose," and advised that this condition may be corrected through the prescription of a higher dose. Similarly, the book recommends that for chronic pain patients, the opioid dose should be "gradually increased to find the best daily dose, as is done with all the other oral drugs." The book discusses the risks of NSAIDs and other drugs at higher doses, but does not explain this risk for opioids.

[119] The College on Problems of Drug Dependence, About the College, http://cpdd.org.

183. Seeking to overturn the criminal conviction of a doctor for illegally prescribing opioids, the Opioid Manufacturers' Front Groups American Pain Foundation and National Pain Foundation argued in an *amicus* brief to the United States Fourth Circuit Court of Appeals that "there is no 'ceiling dose'" for opioids.

184. CDC guidelines on opioid prescribing note that there is "an established body of scientific evidence showing that overdose risk is increased at higher opioid dosages." The CDC also states that there is an increased risk "for opioid [addiction], respiratory depression, and death at higher dosages." That is why the CDC advises doctors to "avoid increasing dosage" to above 90 morphine milligram equivalents per day.

185. Purdue misleadingly promoted OxyContin as being unique among opioids in providing 12 continuous hours of pain relief with one dose. In fact, OxyContin does not last for 12 hours—a fact that Purdue has known at all times relevant to this action. Purdue's own research shows that OxyContin wears off in under six hours in one quarter of patients and in under 10 hours in more than half. This is because OxyContin tablets release approximately 40% of their active medicine immediately, after which release tapers. This triggers a powerful initial response, but provides little or no pain relief at the end of the dosing period, when less medicine is released. This phenomenon is known as "end of dose" failure, and the FDA found in 2008 that a "substantial proportion" of chronic pain patients taking OxyContin experience it. This not only renders Purdue's promise of 12 hours of relief false and deceptive, it also makes OxyContin more dangerous because the declining pain relief patients experience toward the end of each dosing period drives them to take more OxyContin before the next dosing period begins, quickly increasing the amount of drug they are taking and spurring growing dependence. Frequent higher doses are the perfect recipe for an overdose.

186. Purdue's competitors were aware of this problem. For example, Endo ran advertisements for Opana ER referring to "real" 12-hour dosing. Nevertheless, Purdue falsely promoted OxyContin as if it were effective for a full 12 hours. Purdue's sales representatives continue to tell doctors that OxyContin lasts a full 12 hours. Front Groups supported by Purdue echoed these representations.

6. Misrepresentation: Abuse-deterrent Opioid Formulations Are Good at Preventing Abuse

187. Defendants' deceptive marketing of the so-called abuse-deterrent properties of some of their opioids has created false impressions that these opioids can prevent addiction and abuse.

188. For example, Endo's advertisements for the 2012 reformulation of Opana ER claimed that it was designed to be crush resistant, in a way that suggested it was more difficult to abuse. This claim was false. The FDA warned in a 2013 letter that Opana ER Extended-Release Tablets' "extended-release features can be compromised, causing the medication to 'dose dump,' when subject to . . . forms of manipulation such as cutting, grinding, or chewing, followed by swallowing."[120] Also troubling, Opana ER can be prepared for snorting using commonly available methods and "readily prepared for injection."[121] The letter discussed "the troubling possibility that a higher (and rising) percentage of [Opana ER Extended-Release Tablet] abuse is occurring via injection."[122] Endo's own studies, which it failed to disclose, showed that Opana ER could still be ground and chewed. In June 2017, the FDA requested that Opana ER be removed from the market.

[120] Letter from Janet Woodcock, M.D., Dir., Ctr. For Drug Evaluation and Research, U.S. Food and Drug Admin., U.S. Dep't of Health and Human Servs., to Robert Barto, Vice President, Reg. Affairs, Endo Pharm. Inc. (May 10, 2013), at 5.
[121] *Id*. at 6.
[122] *Id*. at 6 n.21.

7. Misrepresentation: Opioids Are Effective for The Treatment of Chronic Pain

189. To convince doctors and patients that opioids should be used to treat chronic pain, the Opioid Manufacturers also had to persuade them that there was a significant upside to long-term opioid use. But as the CDC guidelines on opioid prescribing make clear, "[n]o evidence shows a long-term benefit of opioids in pain and function versus no opioids for chronic pain with outcomes examined at least 1 year later" and that other treatments were more or equally beneficial and less harmful than long-term opioid use.[123] The FDA, too, has recognized the lack of evidence to support long- term opioid use. Despite this, Defendants falsely and misleadingly touted the benefits of long-term opioid use and falsely and misleadingly suggested that these benefits were supported by scientific evidence.

190. For example, Actavis distributed an advertisement claiming that the use of Kadian to treat chronic pain would allow patients to return to work, relieve "stress on your body and your mental health," and help patients enjoy their lives.

191. Endo distributed advertisements that claimed that the use of Opana ER for chronic pain would allow patients to perform demanding tasks like construction work or work as a chef and portrayed seemingly healthy, unimpaired subjects.

192. Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as "a fact" that "opioids may make it easier for people to live normally." The guide lists expected functional improvements from opioid use, including sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs.

[123] *Id*. at 15.

193. Janssen promoted Ultracet for everyday chronic pain and distributed posters, for display in doctors' offices, of patients in active professions; the caption read, "Pain doesn't fit into their schedules."

194. Sponsored and distributed by Cephalon, Endo, and Purdue, the guidelines *Responsible Opioid Prescribing* (2007) taught prescribers that relief of pain by opioids is effective at improving patients' functioning.

195. Cephalon and Purdue sponsored American Pain Foundation's *Treatment Options: A Guide for People Living with Pain* (2007), which counseled patients that opioids "give [pain patients] a quality of life we deserve." This publication is still available online.

196. Endo's National Initiative on Pain Control website, "PainKnowledge.org," claimed in 2009 that with opioids, "your level of function should improve; you may find you are now able to participate in activities of daily living, such as work and hobbies, that you were not able to enjoy when your pain was worse." Elsewhere, the website touted improved quality of life (as well as "improved function") as benefits of opioid therapy. The grant request that Endo approved for this project specifically indicated National Initiative on Pain Control's intent to make misleading claims about function, and Endo closely tracked visits to the site.

197. Endo was the sole sponsor, through National Initiative on Pain Control, of a series of continuing medical education programs entitled "Persistent Pain in the Older Patient."[124] One continuing medical education, disseminated via webcast, claimed that chronic opioid therapy has been "shown to reduce pain and improve depressive symptoms and cognitive functioning."

198. Janssen sponsored and funded a multimedia patient education campaign called "Let's Talk Pain." One feature of the campaign was to complain that patients were under-treated.

[124] *E.g.*, NIPC, Persistent Pain and the Older Patient (2007), https://www.painedu.org/Downloads/NIPC/Activities/B173_Providence_RI_%20I nvite.pdf.

In 2009, a Janssen-sponsored website, part of the "Let's Talk Pain" campaign, featured an interview edited by Janssen claiming that opioids allowed a patient to "continue to function."

199. Purdue sponsored the development and distribution of American Pain Foundation's *A Policymaker's Guide to Understanding Pain & Its Management*, which claimed that "[m]ultiple clinical studies" have shown that opioids are effective in improving "[d]aily function," "[p]sychological health," and "[o]verall health-related quality of life for chronic pain." The Policymaker's Guide was originally published in 2011.

200. Purdue's, Cephalon's, Endo's, and Janssen's sales representatives have conveyed and continue to convey the message that opioids will improve patient function.

201. As the FDA and other agencies have made clear for years, these claims have no support in the scientific literature.

202. In 2010, the FDA warned Actavis, in response to its advertising of Kadian, that "we are not aware of substantial evidence or substantial clinical experience demonstrating that the magnitude of the effect of the drug [Kadian] has in alleviating pain, taken together with any drug-related side effects patients may experience . . . results in any overall positive impact on a patient's work, physical and mental functioning, daily activities, or enjoyment of life." And in 2008, the FDA sent a warning letter to an opioid manufacturer, making it clear "that [the claim that] patients who are treated with the drug experience an improvement in their overall function, social function, and ability to perform daily activities . . . has not been demonstrated by substantial evidence or substantial clinical experience."

8. Misrepresentation: Alternatives Are As Risky As or Risker Than Opioids

203. The Opioid Manufacturers also falsely and misleadingly emphasized or exaggerated the risks of competing medications like NSAIDs, which are used to treat pain and

inflammation, in order to steer doctors and patients to look to opioids first for the treatment of chronic pain. Once again, these misrepresentations by the Opioid Manufacturers contravene pronouncements by and guidance from the FDA and CDC based on the scientific evidence. Indeed, the FDA changed the labels for extended release and long-acting opioids in 2013 and immediate release opioids in 2016 to state that opioids should only be used as a last resort "in patients for which alternative treatment options," like non-opioid drugs, "are inadequate." And the CDC opioid prescribing guidelines state that NSAIDs – not opioids – should be the first-line treatment for chronic pain, particularly arthritis and lower-back pain.

9. Misrepresentation: Fentanyl Is Safe for Chronic Pain

204. Fentanyl is an extremely strong opioid that is indicated only to treat cancer patients with severe pain for whom other opioids have ceased being effective. Fentanyl is "100 times more powerful than morphine."[125]

205. Cephalon deceptively marketed its brand-name fentanyl opioids, Actiq and Fentora, for chronic pain even though the FDA has expressly limited their use to the treatment of cancer pain in opioid-tolerant individuals. Both Actiq and Fentora are extremely powerful fentanyl-based immediate release opioids. Neither is approved for or has been shown to be safe or effective for chronic pain. Indeed, the FDA expressly prohibited Cephalon from marketing Actiq for anything but cancer pain, and refused to approve Fentora for the treatment of chronic pain because of the potential harm, including the high risk of "serious and life-threatening adverse events" and abuse. The FDA also issued a Public Health Advisory in 2007 emphasizing that Fentora should only be used for cancer patients who are opioid-tolerant and should not be

[125] Rich Lord et al., Overdosed: How Doctors Wrote the Script for An Epidemic, Pittsburgh Post-Gazette (May 22, 2016), http://bit.ly/2wkVP6y.

used for any other conditions, such as migraines, post-operative pain, or pain due to injury.[126] Specifically, the FDA advised that Fentora "is only approved for breakthrough cancer pain in patients who are *opioid-tolerant*."[127]

206. Despite this, Cephalon conducted and continues to conduct a well-funded campaign to promote Actiq and Fentora for chronic pain and other non-cancer conditions for which it was not approved, appropriate, and for which it is not safe. As part of this campaign, Cephalon used continuing medical education programs, speaker programs, key opinion leaders, journal supplements, and detailing by its sales representatives to give doctors the false impression that Actiq and Fentora are safe and effective for treating non-cancer pain.

207. For example, Cephalon paid to have a continuing medical education it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The continuing medical education instructed doctors that "[c]linically, broad classification of pain syndromes as either cancer- or non-cancer-related has limited utility" and recommended Actiq and Fentora for patients with chronic pain.

208. Cephalon's sales representatives set up hundreds of speaker programs for doctors, including many non-oncologists, which promoted Actiq and Fentora for the treatment of non-cancer pain.

209. In December 2011, Cephalon widely disseminated a journal supplement entitled "Special Report: An Integrated Risk Evaluation and Mitigation Strategy for Fentanyl Buccal Tablet (FENTORA) and Oral Transmucosal Fentanyl Citrate (ACTIQ)" to Anesthesiology News and Pain Medicine News – two publications that are sent to thousands of anesthesiologists and

[126] *See* U.S. Food & Drug Admin., Public Health Advisory: Important Information for the Safe Use of Fentora (fentanyl buccal tablets) (Sept. 26, 2007), http://bit.ly/2leUcDp.
[127] *Id*.

other medical professionals. The Special Report openly promotes Fentora for "multiple causes of pain" – and not just cancer pain.

210. Cephalon's deceptive marketing gave doctors and patients the false impression that Actiq and Fentora were not only safe and effective for treating chronic pain, but were also approved by the FDA for such uses.

10. Opioid Manufacturers Cover Up That Their Drugs Are Being Diverted to The Illegal Market

211. Purdue unlawfully and unfairly failed to report or address illicit and unlawful prescribing of its drugs, despite knowing about it for years. Purdue's sales representatives have maintained a database since 2002 of doctors suspected of inappropriately prescribing its drugs. Purdue never reported these doctors to the DEA, as required by federal law. In an interview with the *Los Angeles Times*, Purdue's senior compliance officer acknowledged that in five years of investigating suspicious pharmacies, Purdue failed to take action – even where Purdue employees personally witnessed the diversion of its drugs.

212. The same was true of prescribers; despite its knowledge of illegal prescribing, Purdue did not report that a Los Angeles clinic prescribed more than 1.1 million OxyContin tablets and that Purdue's district manager described it internally as "an organized drug ring" until years after law enforcement had already shut the pharmacy down. In doing so, Purdue protected its own profits at the expense of public health and safety.[128]

213. Like Purdue, Endo has been cited for its failure to set up an effective system for identifying and reporting suspicious prescribing. In its settlement agreement with Endo, the State of New York found that Endo failed to require sales representatives to report signs of abuse,

[128] Harriet Ryan et al., More Than 1 Million OxyContin Pills Ended Up in the Hands of Criminals and Addicts. What the Drugmaker Knew, L.A. Times, July 10, 2016, http://www.latimes.com/projects/la-me-oxycontin-part2/.

diversion, and inappropriate prescribing, and failed to prevent sales representatives from visiting prescribers whose suspicious conduct had caused them to be placed on a no-call list.

11. Opioid Manufacturers Targeted Susceptible Prescribers and Vulnerable Patient Populations.

214. As a part of their deceptive marketing scheme, the Opioid Manufacturers identified and targeted susceptible prescribers and vulnerable patient populations in the U.S., including this Commonwealth. For example, the Opioid Manufacturers focused their deceptive marketing on primary care doctors, who were more likely to treat chronic pain patients and prescribe them drugs, but were less likely to be educated about treating pain and the risks and benefits of opioids and were therefore more likely to accept the Opioid Manufacturers' misrepresentations without question.

215. The Opioid Manufacturers also targeted vulnerable patient populations like the elderly and veterans, who tend to suffer from chronic pain. The Opioid Manufacturers targeted these vulnerable patients even though the risks of long-term opioid use were significantly greater for them. For example, the CDC has found that elderly patients who take opioids suffer from elevated fall and fracture risks, reduced renal function and medication clearance, and a smaller window between safe and unsafe dosages. The CDC states that there must be "additional caution and increased monitoring" to minimize the risks of opioid use in elderly patients. The same is true for veterans, who are more likely to use anti-anxiety drugs (benzodiazepines) for post-traumatic stress disorder, which interact dangerously with opioids.

D. The Opioid Distributors Facilitated Diversion Of Prescription Opioids to The Illegal Market

1. Diversion of Opioids from Licensed Prescribers to The Illegal Market Is Fueling the Opioid Epidemic

216. A small minority of doctors are fueling a huge portion of the opioid epidemic. "U.S. Attorney David Hickton, co-chair of the National Heroin Task Force, placed some of the blame for an epidemic of related problems of heroin and opioid pill abuse on the small percentage of doctors who we call drug dealers with white coats."[129] Doctors who are willing to write almost anyone a prescription for opioids are sometimes referred to as "script doctors" or "script docs."[130]

217. Despite being warned "time and again that pain pills can addict and kill, hundreds of doctors … wantonly prescribed painkillers, setting the stage for the worst drug epidemic in U.S. history as brand-name opioids joined with cheap heroin."[131] For example, the *Pittsburg Post-Gazette* reports, "Dr. Gary A. Shearer continued to prescribe painkillers, even as 14 of his patients died of drug overdoses …. Maryland psychiatrist Patricia A. Newton kept prescribing to a struggling addict … until that patient turned up, unconscious, in a Maryland hospital bathroom with a syringe and 545 pills. … Physician Michael B. Rosen was prescribing nearly 1,000 highly addictive pills per month to a patient who told a Pennsylvania detective that he 'did not have any serious pain,' but could get 'whatever he wanted' from 'Dr. Feel Good.'"[132]

218. The National Survey on Drug Use and Health (2006) found that 19.1% of recreational opioid users said they got their drugs from a single doctor who was willing to prescribe them.

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[129] Rich Lord et al., Overdosed: How Doctors Wrote the Script for An Epidemic, Pittsburgh Post-Gazette (May 22, 2016), http://bit.ly/2wkVP6y.
[130] James A. Inciardi, PhD et al., Prescription Opioid Abuse and Diversion in an Urban Community: The Results of an Ultrarapid Assessment, Pain Medicine, Volume 10, Issue 3, 1 April 2009, Pages 537–548, http://bit.ly/2BFKg0U.
[131] Lord, *supra* note 129.
[132] *Id*.

219. In Kentucky, one of the hardest hit by the opioid crisis, 1.2% of doctors ultimately faced some sort of disciplinary action for overprescribing opioids, when the state cracked down, starting in 2011.[133] As a result of Kentucky's recent enforcement efforts, "Opioid prescribing in Kentucky dropped dramatically, and drug overdoses bucked the national trend by edging downward."[134] In contrast, Pennsylvania saw only a tiny drop in opioid prescribing in recent years, while opioid overdoses in the state "climbed relentlessly."[135] "Pennsylvania's medical licensing boards don't have access to data on how individual physicians are prescribing," and so they have taken little disciplinary action against doctors who overprescribed opioids.[136] The *Pittsburgh Post-Gazette* compared enforcement efforts across various states and found: when it comes to reducing opioid abuse, "Getting tough on doctors works."[137]

220. In a study of opioid overdose deaths in Utah in 2013, the decedent's healthcare provider was the primary source of the opioids in 92% of the deaths.[138]

2. Problem Pharmacies Are Also Complicit in Fueling the Opioid Epidemic

221. Certain bad-actor pharmacies or pharmacy employees are responsible for diverting substantial amounts of opioids from the lawful market to the black market.

222. Pharmacy employees who are willing to break the law to sell high-value pills on the black market use a variety of methods to illegally acquire pills from their employer. Some pharmacists or pharmacy technicians are subtle, and skim a few pills each time a patient fills an opioid prescription.[139] The patient will be unlikely to notice if only one or two pills are missing.

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[133] According to an analysis by the Pittsburgh Post-Gazette, looking at the years 2011 to 2015. *See id.*
[134] *Id*.
[135] *Id*.
[136] *Id*.
[137] *Id*.
[138] Johnson EM, Lanier WA, Merrill RM, Unintentional prescription opioid-related overdose deaths: description of decedents by next of kin or best contact, Utah, 2008-2009. J. Gen Intern Med. (Apr. 2013), 28(4):522-9.
[139] Jamie Almond, Detective, Pharmacy Crimes, (Feb. 2014), http://bit.ly/2BsgiJK.

Bolder pharmacy employees steal entire bottles from the pharmacy inventory.[140] Pharmacists may also create fake pharmacy accounts in the name of deceased patients or via identity theft, and use the fake accounts to fill prescriptions for opioids.[141]

223. Sometimes entire pharmacies are just "fronts for criminal drug rings."[142] For example, two brothers who owned a Los Angeles pharmacy, Global Compounding, were found guilty in 2017 of operating "a years-long narcotic drug trafficking … conspiracy that illegally sold prescription narcotics to black market customers across the United States."[143] "These defendants used their pharmacy as a front for drug dealing, and they used multiple bank accounts to conceal their illicit proceeds," said United States Attorney Eileen M. Decker.[144] The brothers were caught after years of shipping thousands of oxycodone pills to organized crime operations in Columbus, Ohio.[145] To conceal these black market drugs sales, the brothers "used their pharmacy to generate records that falsely indicated that prescriptions had been filled in the names of identity theft victims."[146] The brothers' pharmacy ordered nearly 100,000 oxycodone pills from legitimate prescription drug distributors, yet "reported only half of those pills to state authorities who track prescription drug sales."[147] And there was "a 15-month period with no reporting at all."[148] Although the pharmacy concealed many of its suspicious orders from state regulators, the drug distributors had all the data and knew exactly how many pills the pharmacy was ordering.

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[140] *Id*.
[141] *Id*.
[142] Bill Whitaker, Whistleblowers: DEA Attorneys Went Easy on McKesson, The Country's Largest Drug Distributor, CBS News (Dec. 17, 2017), http://cbsn.ws/2B2ddno.
[143] Department of Justice, Owners of West L.A. Pharmacy Found Guilty in Sweeping Scheme to Illegally Distribute Prescription Narcotics (Jan. 23, 2017), http://bit.ly/2D0XEZF.
[144] *Id*.
[145] *Id*.
[146] *Id*.
[147] *Id*.
[148] *Id*.

3. Drug Distributors Have a Non-Delegable Duty to Prevent Shipment of Suspicious Orders of Opioids and Report Them to The DEA

224. The Controlled Substances Act is the "legal cornerstone" of the federal government's war against drug abuse.[149] To enforce the Controlled Substances Act, the Drug Enforcement Administration divides categories of drugs into tiers, called "schedules," with lower-numbered schedules being more highly regulated.[150] In deciding which drugs should be in which "schedule," the DEA considers four factors: the drug's "(1) potential for abuse, (2) safety, (3) addictive potential and (4) whether or not it has any legitimate medical applications."[151]

225. Schedule I drugs are substances that have no federally-recognized medical use, high risk of abuse, and severe addictive potential, and are extremely dangerous.[152] Schedule I drugs include: heroin and ecstasy.[153]

226. Schedule II drugs are drugs that are slightly less dangerous and have slightly less abuse potential than Schedule I drugs.[154] Schedule II includes some drugs with federally-recognized medical applications. Drugs on Schedule II include: cocaine, methamphetamine ("meth"), and nearly all opioid medications.

227. Schedule III drugs are defined as having low to moderate abuse potential, such as anabolic steroids.[155] And Schedule IV drugs are defined as having low abuse and addictive potential, such as anti-anxiety medications (Xanax) and sleeping pills (Ambien).[156] Schedule V drugs are the least dangerous controlled substances, and include many cough syrups (such as Robitussin AC).

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[149] American Academy of Pediatrics, Understanding Drug Schedules, HealthyChildren.org, (Nov. 21, 2015), http://bit.ly/2C09Dtv.
[150] *Id*.
[151] *Id*.
[152] *Id*.
[153] *Id*.
[154] *Id*.
[155] *Id*.
[156] *Id*.

228. Schedule II drugs are the most highly regulated prescription drugs. Pharmacies are not permitted to dispense Schedule II drugs with any refills. Every time a patient asks for a refill, their doctor must write out a new prescription. In contrast, Schedule III and IV drugs may be dispensed with up to 5 refills.

229. For all Schedule II substances, drug distributors must report to the DEA all purchases and shipments, and their current inventory of the drug.[157] This data is stored in the DEA's Automation of Reports and Consolidated Orders System (ARCOS) database.[158]

230. In addition, federal law requires distributors to have a system in place to identify and report "suspicious orders" to the DEA's Office of Diversion Control.[159]

231. "Suspicious orders" include orders of an unusual size or frequency, or deviating substantially from the pharmacy's normal ordering pattern.[160] The DEA has specified that "suspicious orders" include "[g]eographic anomalies," such as a town ordering more drugs that its population could possibly consume.[161] Orders are also "suspicious," says the DEA, if they have an unusual composition, such as "100 percent" of a pharmacy's orders being for opioid medications.[162]

232. In addition to reporting suspicious orders, distributors must also stop shipment on any order which is flagged as suspicious or potentially suspicious.[163]

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[157] Department of Justice, ARCOS Questions & Answers, https://www.deadiversion.usdoj.gov/arcos/faq.htm (last visited Dec. 23, 2017).
[158] *Id*.
[159] 21 C.F.R. § 1301.74(b).
[160] *See* 21 CFR § 1301.74(b).
[161] Larry Cole, A Pharmacist's Obligation: Corresponding Responsibility and Red Flags of Diversion, Quarles & Brady (Aug. 11, 2013), http://bit.ly/2pjxXRY.
[162] *See Southwood Pharmaceuticals, Inc*.; Revocation of Registration, 72 FR 36487-01, 2007 WL 1886484 (July 2, 2007) (DEA enforcement action).
[163] *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487, 36,501 (Drug Enf't Admin. July 3, 2007); *Masters Pharmaceutical, Inc. v. Drug Enforcement Administration*, No. 15-11355 (D.C. Cir. June 30, 2017). The distributor may, however, ship a potentially suspicious order if, after conducting due diligence, the distributor can determine that the order is not likely to be diverted into illegal channels.

4. The Opioid Distributors Breached their Duties to Report and Not Fill Suspicious Orders

233. Because distributors ship such large volumes of controlled substances to pharmacies across the country, they are the first major line of defense in preventing the diversion of controlled substances from legitimate channels into the illicit market. In dereliction of their duties, the Opioid Distributors turned a blind eye to pharmacies that repeatedly placed suspicious orders and failed to report them to the DEA.

234. The Opioid Distributors should have flagged that something was wrong with orders going to certain locales due to the enormous number of pills that were shipped to these locations, relative to their population size. *Vox* reports, "Opioid distributors supplied a ton of these pills, even when they should have known they were going to people who were misusing the drugs. This is backed by data that shows that in some counties and states, there were more prescribed bottles of painkillers than there were people — a sign that something was going very wrong."[164] For example, data for the Cherokee Nation shows that "845 million milligrams of opioids were distributed in the 14 counties that make up the Cherokee Nation."[165] "[I]f you assume an average pill size of 20 milligrams" and an average 30-day supply of pills, this quantity is enough for every tribal member living in the Cherokee Nation to consume nearly 8 bottles of opioid pills.[166] Although Cherokee tribe members make up only 4.5% of Oklahoma's population, "[a]lmost a third of the prescription painkillers distributed in that state went to the Cherokee Nation."[167]

[164] German Lopez, US officials are starting to treat opioid companies like Big Tobacco — and suing them, Vox (Aug. 9, 2017), http://bit.ly/2uq4M20.
[165] *Id*.
[166] *Id.*; Nate Hegyi, Cherokee Nation Sues Wal-Mart, CVS, Walgreens Over Tribal Opioid Crisis, NPR (Aug. 25, 2017), http://n.pr/2BXkguV (177,000 tribal members live in the Cherokee Nation's 14 counties).
[167] Hegyi, *supra* note 166.

235. The Opioid Distributors should have been tipped off to suspicious orders not only by huge order volumes relative to population size, but also by the high proportion of opioids ordered by certain pharmacies. For some pharmacies, all or almost all they ordered were opioids. *The Atlantic* reports, "Eleven drug stores, mostly independents, are scattered about a tiny city of 1,500 people. Many have opened in the past decade—four in the past three years. And prescription pain drugs are one of the best-selling items—the very best seller at some. Most pharmacies here and in surrounding Clay County… sell few items over the counter, focusing on prescriptions and little else. Clay's residents filled prescriptions for 2.2 million doses of hydrocodone and about 617,000 doses of oxycodone in the 12-month period ending last September—that's about 150 doses for every man, woman, and child."[168]

236. Opioid Distributors also should have known something was amiss with pharmacies that had enormous aggregate increases in order volume for opioids. For example, Unique Pain Management, a clinic in an Ohio town of 6,500, increased its monthly order volume for oxycodone from 67,800 doses to 104,400 doses, over a short period.[169] Its distributor didn't even investigate this 54% increase.[170]

237. In the 1990s, the distributors weren't even reporting their drug shipment statistics correctly, let alone flagging suspicious orders for the DEA. A *Washington Post* investigation found that in the 1990s, the Opioid Distributors "had been reporting their drugs sales inconsistently or not at all."[171] Yet, they didn't face disciplinary action from the DEA. John J.

[168] Phil Galewitz, The Pharmacies Thriving in Kentucky's Opioid-Stricken Towns, The Atlantic (Feb. 7, 2017), http://theatln.tc/2lwYKF5.
[169] Lenny Bernstein et al., How drugs intended for patients ended up in the hands of illegal users: 'No one was doing their job', Washington Post (Oct. 22, 2016), http://wapo.st/2BsP31C.
[170] *Id*.
[171] Lenny Bernstein and Scott Higham, Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control, Washington Post (Oct. 22, 2016), http://wapo.st/2kMNO77.

Coleman, the third-ranking administrator at the DEA in the mid-1990s, said in a recent interview that the distributors were "ignored for years and years and years."[172]

238. That changed in 2005, when a new director ascended to lead the DEA's Office of Diversion Control. Joe Rannazzisi, "a street-smart New Yorker who held degrees in pharmacy and law … had begun his career as a DEA street agent and then a supervisor in Detroit before working his way to the top of the diversion office."[173] Finding himself as the nation's chief drug enforcer as the nation faced an ever-expanding opioid epidemic, Rannazzisi decided to focus the DEA's attention on the distributors, who weren't fulfilling their obligation to report and not fill suspicious orders.[174] To Rannazzisi, the distributors were the key link in the supply chain that was fueling the opioid epidemic. While the Opioid Manufacturers were large companies with an obligation to monitor their sales to distributors, they often didn't know where their drugs went after the distributors took over. The distributors, as the middlemen that shipped the drugs to pharmacies all across the country, knew where the drugs went and who was ordering them.[175] And the three largest distributors, McKesson, Cardinal, and AmerisourceBergen supplied 85% of the national drug market.[176] These companies had the internal data to identify the problem pharmacies and prescribers and stop shipping to them.

239. In 2005, Rannazzisi launched the Office of Diversion Control's "Distributor Initiative," and in 2006, "the diversion office sent a letter to distributors across the country, reminding them that they were required by law to ensure that their drugs were not being diverted to the black market."[177] Rannazzisi was putting the distributors on notice that they needed "to

[172] *Id*.
[173] *Id*.
[174] *Id*.
[175] *Id*.
[176] *Id*.
[177] *Id*.

monitor their sales in real time, withhold drug shipments if they detected suspicious activity and report those red flags to the DEA."[178]

240. Frank Younker, "the former DEA supervisor in Cincinnati, said the agency had no other choice" but to go after the Opioid Distributors.[179] 'The distributors could have stopped what was going on, but they didn't," he said. "They were doing the bare minimum. Why would you want to cut off a customer that's paying you $2 million a year? They have sales reps and sales quotas and bonus structures and employees of the month. Everyone was making a lot of money."[180]

241. In 2007, the DEA's diversion office brought "an enforcement case against McKesson — now the nation's largest drug distributor and the fifth-largest corporation in the country. The DEA accused the company of failing to report hundreds of suspicious orders from online pharmacies."[181] As a result of McKesson's actions, "millions of dosage units of controlled substances were diverted from legitimate channels of distribution," according to a Justice Department statement in 2008.[182] McKesson settled the case, agreeing to pay a $13 million fine.[183]

242. Also in 2008, the DEA's diversion office "filed a case against Cardinal Health, another member of the Big Three wholesalers. DEA investigators alleged that the company was sending millions of doses of painkillers to online and retail pharmacies without alerting

[178] *Id*.
[179] *Id*.
[180] *Id*.
[181] *Id*.
[182] *Id*.
[183] *Id*.

investigators to an obvious sign of illegal diversion."[184] Cardinal settled the allegations, agreeing to pay a $34 million fine.[185]

243. At the time, online pharmacies were a huge contributor to the opioid epidemic. But in 2009, "a federal law made it illegal to distribute controlled substances online and required doctors to see their patients face-to-face before writing prescriptions."[186]

244. "In late 2011, Rannazzisi's office filed warrants to yet again inspect the records of a Cardinal warehouse. Investigators alleged that the company was overlooking escalating oxycodone orders from pharmacies in Florida."[187] A *Washington Post* investigative report uncovered "an internal Cardinal email from 2010 showing that the company's own investigator had warned against selling narcotics to Gulf Coast Medical Pharmacy, an independent drugstore in Fort Myers, Fla., citing suspicions that the pills were winding up on the street. Despite the warning, Cardinal hadn't notified the DEA or cut off the supply of drugs. Instead, the company shipped increasing quantities of pain pills to Gulf Coast."[188] In 2011 alone, Cardinal sent more than 2 million doses of oxycodone to Gulf Coast.[189] Cardinal was sending pharmacies of a similar size an average of only 65,000 doses per year, according to Cardinal's own internal data.[190] "I had the case of my dreams" against Cardinal, Rannazzisi said.

245. After being tipped off about the DEA investigation, rather than fix the problem, Cardinal called in its lobbyists, who had contacts within the current Bush administration.[191] As Rannazzisi was getting ready to file an enforcement action to suspend Cardinal's license to distribute opioids and other drugs, he received a call from James M. Cole, the Deputy Attorney

[184] *Id*.
[185] *Id*.
[186] *Id*.
[187] *Id*.
[188] *Id*.
[189] *Id*.
[190] *Id*.
[191] *Id*.

General at the Department of Justice, demanding that Rannazzisi come meet with Cole in Washington before taking any action.[192] After arriving in Cole's office, Rannazzisi said, "I've done hundreds of these cases, and I've never been called over to the Justice Department to explain myself."[193] Rannazzisi demanded to know why this case was any different.[194] From there, the meeting with Cole became "very adversarial."[195]

246. Undeterred, Rannazzisi decided to file against Cardinal anyway.[196] Cardinal Health settled the case, agreeing to pay a $44 million fine for failure to report suspicious opioid orders.[197]

247. Between 2012 – the year Rannazzisi filed against Cardinal – and 2015, Cardinal Health increased its lobbying spending by 82% compared to the previous four-year period.[198] Jon Giacomin, the CEO of Cardinal Health, is chairman of the board of directors at Healthcare Distribution Alliance, a pro-distributor lobbyist organization.[199] Between 2012 and 2014, Healthcare Distribution Alliance increased its lobbying spending by 40% compared to the previous period.[200] Both Cardinal and Healthcare Distribution Alliance heavily lobbied Congress to make it more difficult for the DEA to bring enforcement actions against distributors.[201]

248. In September 2014, Congressman Tom Marino, one of the distributor's top advocates in Congress, pressured the DEA Administrator, the head of the entire agency, to take

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[192] *Id*.
[193] *Id*.
[194] *Id*.
[195] *Id*.
[196] *Id*.
[197] Lenny Bernstein and Scott Higham, Cardinal Health fined $44 million for opioid reporting violations, Washington Post (Jan. 11, 2017), http://wapo.st/2kMED6y.
[198] *See* Center for Responsive Politics, Cardinal Health Summary, http://bit.ly/2C0G7Sh (last visited Dec. 24, 2017) (Cardinal's spending increased from $4.757 million to $8.655 million).
[199] Healthcare Distribution Alliance, http://bit.ly/2pnuwtv (last visited Dec. 24, 2017).
[200] Center for Responsive Politics, Healthcare Distribution Alliance, http://bit.ly/2BINZed (last visited Dec. 24, 2017).
[201] Bernstein, Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control, *supra* note 171.

action against Rannazzisi, who Marino saw as too aggressive against industry.[202] Facing increasing pressure over the course of the next year, the DEA Administrator removed Rannazzisi as chief of the agency's Office of Diversion Control in August 2015.[203]

249. President Trump nominated Tom Marino to be his drug czar in 2017 to lead the fight against opioid abuse. Marino was forced to withdraw his name "in the wake of reports that as a congressman he did the bidding of the pharmaceutical industry."[204]

250. While Rannazzisi was still at the DEA's diversion enforcement office, the agency was building a huge case against McKesson, the nation's largest distributor. "By 2014, [DEA] investigators said they could show that the company had failed to report suspicious orders involving millions of highly addictive painkillers sent to drugstores from Sacramento, Calif., to Lakeland, Fla. Some of those went to corrupt pharmacies that supplied drug rings."[205] David Schiller, who led the McKesson investigation, "and members of his team wanted to fine the company more than $1 billion. More than anything else, they wanted to bring the first-ever criminal case against a drug distribution company, maybe even walk an executive in handcuffs out of McKesson's towering San Francisco headquarters to send a message to the rest of the industry."[206] Schiller said, "This is the best case we've ever had against a major distributor in the history of the Drug Enforcement Administration."[207]

251. "DEA investigators, agents and supervisors who worked on the McKesson case said the company paid little or no attention to the unusually large and frequent orders placed by

[202] Scott Highman and Lenny Bernstein, The drug industry's triumph over the DEA, Chicago Tribune (Oct. 15, 2017), http://trib.in/2B7CnNL.
[203] Bernstein, Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control, *supra* note 171.
[204] Peter Baker, Tom Marino, Drug Czar Nominee, Withdraws in Latest Setback for Trump's Opioid Fight, N.Y. Times (Oct. 17, 2017), http://nyti.ms/2gMOJT9.
[205] Lenny Bernstein, 'We feel like our system was hijacked': DEA agents say a huge opioid case ended in a whimper, Washington Post (Dec. 17, 2017), http://wapo.st/2BBbmpa.
[206] *Id*.
[207] *Id*.

pharmacies, some of them knowingly supplying drug rings."[208] To avoid its obligation to report suspicious orders to the DEA, McKesson defined a "suspicious order" as one where a pharmacy's order volume went over the pharmacy's drug quota by a certain percentage. These quotas, or "thresholds," were numbers assigned to each pharmacy internally by McKesson. To ensure opioid orders wouldn't go over the threshold, McKesson just kept raising the pharmacies' thresholds. A DEA investigator told *60 Minutes* that "to get around reporting suspiciously large orders, at the time, McKesson would simply raise the limit a pharmacy was allowed. No order, no matter how large, was ever reported as suspicious."[209]

252. For example, Jeffrey Clawson, a pharmacist in Brighton, Colorado, repeatedly bumped up against his thresholds, so McKesson just kept raising them. Brighton is a small town with a population of only 38,000, yet Clawson was selling as many as 2,000 opioid pills per day.[210] "[T]he DEA's Denver field division began a criminal investigation into Clawson, making undercover buys and monitoring the size of his drug purchases. Most of the drugs came from McKesson's warehouse in Aurora, northeast of Denver, records show. Under federal law, McKesson is required to notify the DEA about any orders of unusual size, frequency or pattern and hold off on shipping the drugs until those issues are resolved."[211] Yet, McKesson never reported Clawson to the DEA nor did they stop shipping to Clawson.[212] The DEA investigator who worked Clawson's case says, "We … have a pharmacy in a small town out in Colorado, 200 miles from Denver, that is getting the same number of pills or perhaps exceeding a pharmacy that is located next to a medical center in the city of Denver…. There was no legitimate reason

[208] *Id*.
[209] Bill Whitaker, Whistleblowers: DEA Attorneys Went Easy on McKesson, CBS News (Dec. 17, 2017), http://cbsn.ws/2B2ddno.
[210] Lenny Bernstein, 'We feel like our system was hijacked', *supra* note 205.
[211] *Id*.
[212] *Id*.

for that pharmacy in that little town in remote Colorado to be getting hundreds of thousands of pills over a several-year period. None. There was no justifiable reason."[213] "Clawson ordered so much oxycodone that he repeatedly bumped up against thresholds McKesson had set for his pharmacy. The company raised those limits and sent him more …"[214] One DEA investigator said that McKesson "would raise thresholds so pharmacies could order more pills without setting off suspicious monitoring alarms inside the company."[215]

253. Clawson's order volume should have set off numerous red flags. A grand jury, in indicting Clawson, found, "From 2008-2011, the percentage increase for oxycodone 30 mg orders supplied by McKesson to [Clawson] was approximately 1,469%."[216]

254. Beyond Colorado, DEA "investigators found that McKesson warehouses in Livonia, Mich., and Washington Court House, Ohio, were supplying pharmacies that sold to criminal drug rings."[217] The DEA diversion office, helmed by Rannazzisi, demanded in 2014 that McKesson surrender its licenses to distribute drugs for five of its warehouses, which were implicated in supplying criminal drug rings.[218] McKesson refused.

255. In September 2015, one month after Rannazzisi was removed as chief of the DEA's diversion enforcement office, McKesson reached a settlement with the government that did *not* require it to surrender its warehouse licenses.[219] McKesson agreed to pay a fine of $150 million, which fell far short of the $1 billion that the DEA had wanted to seek while headed by Rannazzisi.[220]

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[213] *Id*.
[214] *Id*.
[215] *Id*.
[216] *Id*.
[217] *Id*.
[218] *Id*.
[219] *Id*.
[220] *Id*.

256. McKesson earns $200 *billion* per year in revenue, so a fine of only $150 million is relatively trivial for McKesson to pay.[221] Schilling, the lead investigator for the DEA, says that McKesson received a level of special treatment that he'd never seen before in his 30-year career, and pointed out that "the $150 million fine was only about $50 million more than McKesson CEO, John Hammergren's compensation last year."[222] New Hampshire senator, Maggie Hassan, says that if our country wants to end the opioid epidemic, "one of the things we have to do is begin to hold the pharmaceutical companies accountable for this. And right now, when you see a fine for the McKesson Company of $150 million when they make a $100 million a week in profits, that isn't gonna do it."[223]

E. Consequences of the Defendants' Actions

257. As the Opioid Manufacturers successfully convinced more and more doctors and patients that opioids were safe and effective for chronic pain, the number of prescriptions for opioids in the United States rose dramatically.

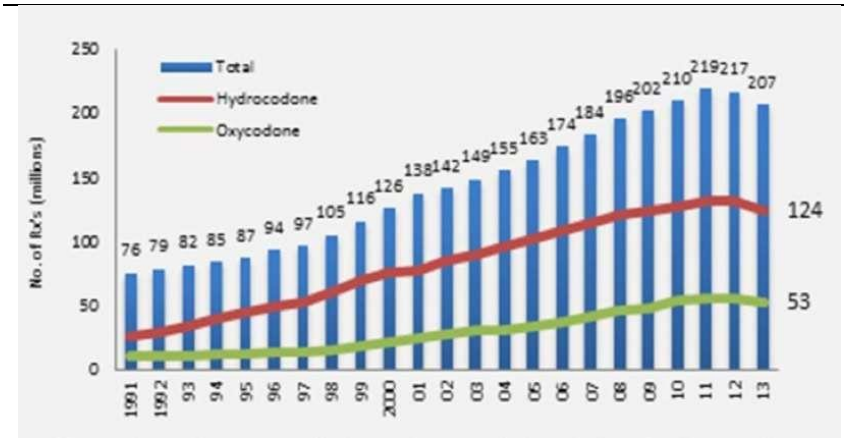

Figure: Opioid Prescriptions Dispensed by US Retail Pharmacies from 1991 to 2013

[221] *Id*.
[222] Bill Whitaker, Whistleblowers: DEA Attorneys Went Easy on McKesson, *supra* note 209.
[223] *Id*.

258. The concomitant rates of opioid abuse and addiction rose as well. Certain doctors and pharmacies sought to exploit this increasing demand for prescription opioids. The DEA and Plaintiffs' police force could not keep pace with the rising rates of drug trafficking and diversion of opioids from legitimate sources. Despite knowing about many suspicious orders, the Opioid Distributors did not report suspicious patterns of opioid orders to the DEA or Plaintiffs' police force, continuing to profit from these large volume buyers who were clearly diverting drugs to the black market.

259. As a result of the wide availability of prescription opioids, addiction rates skyrocketed.

1. Dramatic Rise in Opioid Addiction

260. A recent study found that between 2010 and 2016 alone, the rate of opioid addiction in the United States increased by 493%.[224]

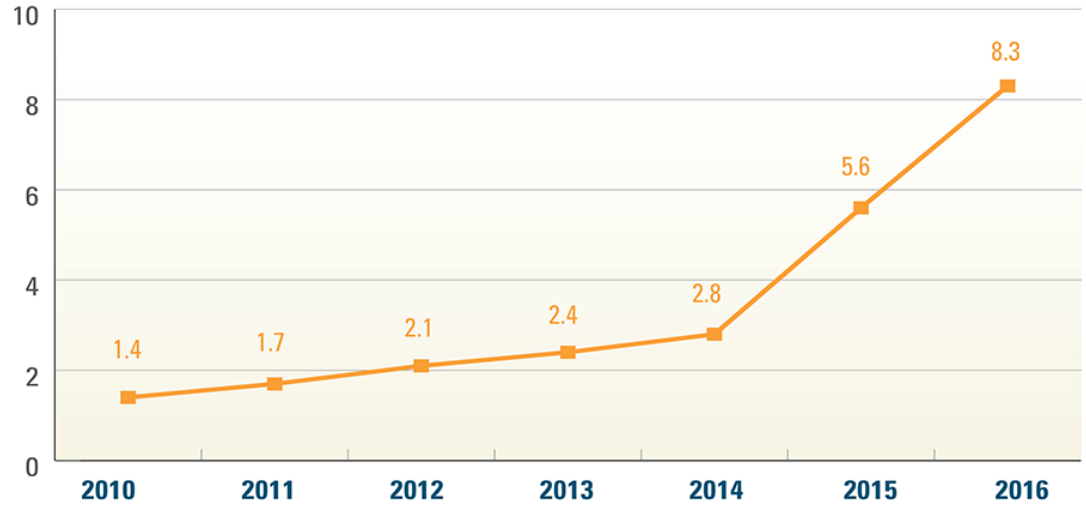

Figure: Opioid addiction rate between 2010 and 2016 (per 1,000 people)

[224] Nadia Kounang, Opioid addiction rates continue to skyrocket, CNN (June 29, 2017), http://cnn.it/2sW83DJ.

2. Overdose deaths

261. In 2011, a statement by the CDC noted that the death toll from overdoses of prescription opioids had more than tripled in the past decade.

262. Prescription opioids account for approximately 70% of fatal prescription drug overdoses.[225]

263. Ninety-one Americans die every day from an opioid overdose.[226]

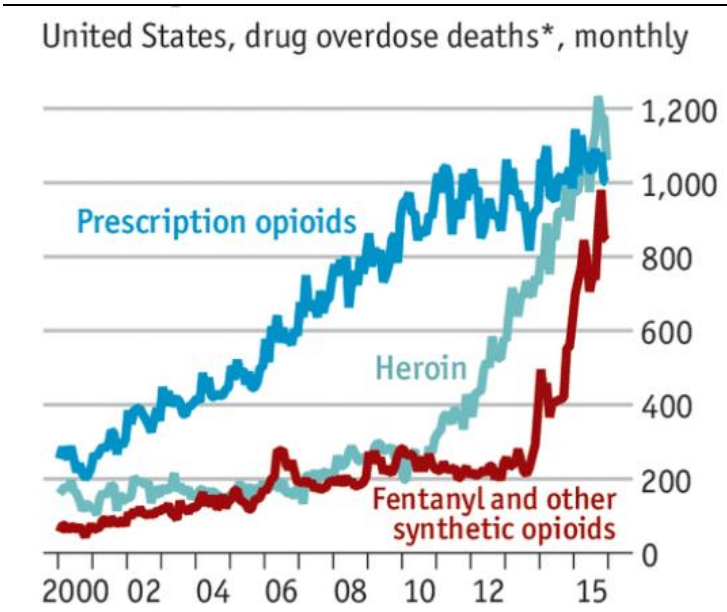

Figure: Increase in monthly opioid deaths from 2000 to 2015

264. The *N.Y. Times* reports, "The current opioid epidemic is the deadliest drug crisis in American history. Overdoses, fueled by opioids, are the leading cause of death for Americans under 50 years old — killing roughly 64,000 people [per] year, more than guns or car accidents…"[227] "If nothing is done, we can expect a lot of people to die: A forecast by STAT

[225] Centers for Disease Control and Prevention, National Center for Health Statistics. Multiple Cause of Death 1999-2013 on CDC WONDER Online Database, released 2015. 2015. Available at: http://wonder-cdc.gov/mcd-icd10.html.
[226] CDC: Opioid Overdose: Opioid Basics: Understanding the Epidemic. https://www.cdc.gov/drugoverdose/epidemic/index.html.
[227] Maya Salam, The Opioid Epidemic: A Crisis Years in the Making, N.Y. Times (Oct. 26, 2017), http://nyti.ms/2zJXHr7.

concluded that as many as 650,000 people will die over the next 10 years from opioid overdoses — more than the entire city of Baltimore. The US risks losing the equivalent of a whole American city in just one decade."[228]

265. For every fatal opioid overdose, there are approximately 30 nonfatal overdoses.[229] These nonfatal overdoses require prompt medical intervention by first responders and emergency treatment at hospitals. Typically, the initial treatment at the scene of the overdose is the administration of naloxone or Narcan, which blocks the effects of an opioid overdose, giving the first responders time to get the patient to a hospital. The rates of hospitalization due to opioid overdose have increased dramatically in the U.S. from 1993 to 2012, growing from 116.7 inpatient stays per 100,000 people to 295.6 inpatient stays per 100,000, an increase of 153%.[230]

266. Alarmingly, even after a nonfatal overdose, opioids continue to be prescribed. For example, a 2000-2012 study[231] reported high rates of opioid prescribing for patients even after they had sustained a nonfatal opioid overdose.

3. Increased heroin addiction and overdose

267. Opioids are a gateway to heroin use. The CDC has identified addiction to prescription pain medication as the strongest risk factor for heroin addiction. People who are addicted to prescription opioid painkillers are forty times more likely to become addicted to heroin.[232]

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[228] German Lopez, The opioid epidemic, explained, Vox (Dec. 21, 2017), http://bit.ly/2wpP8jp.
[229] Frazier W, et al., Medication-Assisted Treatment and Opioid Use Before and After Overdose in Pennsylvania Medicaid, JAMA (Aug. 22, 2017), 318(8):750-752.
[230] Owens, P. L., M. L. Barrett, A. J. Weiss, et al. 2014. Hospital inpatient utilization related to opioid overuse among adults, 1993–2012 (Statistical Brief #177). http://www.hcup-us.ahrq.gov/reports/statbriefs/sb177-Hospitalizations-for-Opioid-Overuse.pdf.
[231] Larochelle MR, Liebschutz JM, Zhang F, et al., Opioid prescribing after nonfatal overdose and association with repeated overdose: a cohort study. Ann Intern. Med. (2016), 164(1):1-9.
[232] *See* Ctrs. for Disease Control and Prevention, U.S. Dep't of Health and Human Servs., Today's Heroin Epidemic, https://www.cdc.gov/vitalsigns/heroin/index.html (last updated July 7, 2015).

268. The *Pittsburgh Post-Gazette* reports, "When Valerie Mack found her brother, Sammy, 50, dead on the floor of his bedroom, she knew that he likely wouldn't have found his way to heroin if he hadn't been injured months earlier in a motorcycle accident and been prescribed [opioid] painkillers."[233] The *Post-Gazette* notes, "The heroin problem wouldn't be one-tenth as bad if we hadn't primed the pump with prescription opioids."[234]

269. Prescription opioids are pharmacologically similar to heroin, and people who get hooked on opioids often switch to the cheaper drug, heroin, as their addiction becomes harder to fund. "Research suggests that misuse of [prescription opioid] drugs may open the door to heroin use. Nearly 80 percent of Americans using heroin (including those in treatment) reported misusing prescription opioids first."[235]

270. The number of heroin users in the United States increased by 145% from 2007 to 2014.[236] Heroin overdoses in the U.S. quintupled from 2000 to 2014.[237]

4. Increased prevalence of needle-borne illnesses (HIV, Hepatitis)

271. People who abuse prescription opioids are 40 times more likely than the general population to use an injectable for either a synthetic opioid or heroin.[238]

272. On January 23, 2015, the Indiana Department of Health began investigating an outbreak of HIV in one of the state's rural communities.[239] The investigation found that the

[233] Lord, *supra* note 125.
[234] *Id*.
[235] National Institute of Drug Abuse, Heroin (July 2017), http://bit.ly/1NpA0Ij.
[236] Center for Behavioral Health Statistics and Quality. 2014 National Survey on Drug Use and Health: detailed tables. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2015.
[237] CDC, Wide-ranging Online Data for Epidemiologic Research (WONDER), Multiple-Cause-of-Death file, 2000–2014. 2015, http://bit.ly/1Z1ZFdF.
[238] Jones CM, Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain relievers—United States, 2002–2004 and 2008–2010. Drug Alcohol Depend. (2013), 132:95–100, https://doi.org/10.1016/j.drugalcdep.2013.01.007.
[239] https://www.cdc.gov/mmWr/preview/mmwrhtml/mm6416a4.htm.

majority of HIV cases were due to residents of the community sharing syringes when injecting the prescription opioid oxymorphone.

273. Needle-sharing can spread not only HIV, but also Hepatitis C. Data from the last 10 years reveals a nationwide increase in Hepatitis C infection among young adults.[240] In May 2017, the CDC released data showing that new Hepatitis C infections have nearly tripled in the past 5 years, largely as a result of opioid-related injection drug use.[241]

> "These new infections are most frequently among young people who transition from taking prescription pills to injecting heroin, which has become cheaper and more easily available in some cases…[I]n turn many -- most, in some communities -- people who inject drugs become infected with hepatitis C," according to the CDC's study lead author, Dr. John Ward.[242]

274. Hepatitis C commonly infects and replicates inside the liver. Up to 70% of people infected with Hepatitis C will develop chronic liver disease.[243]

5. Increase in asthma-related ER visits and deaths

275. Opioids depress the central nervous system, so large doses can substantially slow users' breathing rates. Overdose deaths from opioids often result from the person becoming so sedated that they can no longer regulate their own breathing.

276. Because people with asthma already struggle to get enough oxygen, opioids can exacerbate asthma symptoms. In 2008, an estimated 147,260 adults in Puerto Rico had asthma, which is 15.2% of the population.[244]

277. Opioid-addicted patients with asthma are 600% more likely to be admitted to an emergency room for respiratory problems than non-addicted asthma sufferers.[245] In one study of

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[240] Theresa Watts, MPH, et al., Increased Risk for Mother-to-Infant Transmission of Hepatitis C Virus Among Medicaid Recipients, Morbidity and Mortality Weekly Reports, CDC (Oct. 27, 2017), http://bit.ly/2lhn79Z.
[241] https://www.cdc.gov/mmwr/volumes/66/wr/mm6618a1.htm?s_cid=mm6618a1_w.
[242] *Id.*
[243] CDC, Hepatitis C FAQs for Health Professionals, http://bit.ly/2prWZyr.
[244] CDC's National Asthma Control Program: Asthma in Puerto Rico, https://www.cdc.gov/asthma/stateprofiles/asthma_in_pr.pdf.

inner-city patients admitted to an intensive care unit for asthma-related breathing problems, 56% of admissions appeared to be associated with opioid use.[246]

6. Addiction and death in children

278. Women who become pregnant while addicted to opioids find it difficult to stop taking the drug. Their babies are often born physically addicted to opioids. Every 25 minutes, an opioid addicted baby is born in America.[247]

279. While millions of opioid addicted adults around the nation avoid quitting cold-turkey because of the intense withdrawal effects, newborn babies are left without that option. They are forced to endure painful, debilitating and, at times, life-threatening opioid withdrawal symptoms. These symptoms are known as "neonatal abstinence syndrome," which occurs in up to 94% of newborns whose mothers were addicted to or treated with opioids while pregnant.[248,249]

280. The pain infants experience from neonatal abstinence syndrome is intense. "*It's a panicked, high-pitched wail, almost desperate, a sound you don't forget*," says Kimberly Nelson, a nurse in an intensive care unit, describing the cries of infants experiencing withdrawal.[250]

281. Infants with neonatal abstinence syndrome are at increased risk for admission to the neonatal intensive care unit,[251,252,253] birth complications,[254] the need for pharmacologic treatment,[255,256] and a prolonged hospital stay.[257,258]

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[245] *Id*.
[246] Krantz A.J., Hershow R.C., Pruchand N., et al: Heroin insufflation as a trigger for patients with life-threatening asthma. Chest 2003; 123: pp. 510-517
[247] National institute of Drug Abuse. Dramatic Increases in Maternal Opioid Use and Neonatal Abstinence Syndrome, https://www.drugabuse.gov/related-topics/trends-statistics/infographics/dramatic-increases-in-maternal-opioid-use-neonatal-abstinence-syndrome.
[248] Finnegan LP, Connaughton JF Jr, Kron RE, Emich JP, Neonatal abstinence syndrome: assessment and management, Addict. Dis. (1975), 2:141-158.
[249] Hudak ML, Tan RC, Committee on Drugs, Committee on Fetus and Newborn, Neonatal drug withdrawal. Pediatrics (2012), 129:e540-60.
[250] http://www.reuters.com/investigates/special-report/baby-opioids/.

282. Prolonged hospitalization results in the use of a greater portion of health care resources for the care of infants with the neonatal abstinence syndrome[259] than for those without the syndrome. In 2012, a normal infant with no birth complications stayed in the hospital an average of 2.1 days, with a cost of $3,500, whereas an infant with neonatal abstinence syndrome had an average hospital stay of 16.9 days, with a cost of $66,700.[260] Aggregate hospital charges for all infants with neonatal abstinence syndrome in 2012 were estimated to be $1.5 billion; approximately 80% was financed by Medicaid programs.[261]

7. Burden on local government

283. The societal costs of prescription drug abuse are "huge,"[262] and state and local governments must often bear the brunt of this cost. In total, the economic burden of prescription opioid misuse is $78.5 billion per year, including lost productivity, increased healthcare costs,

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[251] Tolia VN, Patrick SW, Bennett MM, et al., Increasing incidence of the neonatal abstinence syndrome in U.S. neonatal ICUs, N. Engl. J. Med. (2015), 372:2118-2126.
[252] Uebel H, Wright IM, Burns L, et al, Reasons for rehospitalization in children who had neonatal abstinence syndrome, Pediatrics (2015), 136:e811-20.
[253] Cleary BJ, Donnelly JM, Strawbridge JD, et al., Methadone and perinatal outcomes: a retrospective cohort study, Am. J. Obstet. Gynecol. (2011), 204:139.e1-139.e9.
[254] Patrick SW, Davis MM, Lehmann CU, Lehman CU, Cooper WO, Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States 2009 to 2012, J. Perinatol (2015), 35:650-655.
[255] Tolia VN, Patrick SW, Bennett MM, et al., Increasing incidence of the neonatal abstinence syndrome in U.S. neonatal ICUs, N. Engl. J. Med. (2015), 372:2118-2126.
[256] Jansson LM, Velez ML, Infants of drug-dependent mothers, Pediatr. Rev. (2011), 32:5-12.
[257] Lee J, Hulman S, Musci M Jr, Stang E, Neonatal abstinence syndrome: influence of a combined inpatient/outpatient methadone treatment regimen on the average length of stay of a Medicaid NICU population, Popul. Health Manag. (2015), 18:392-397.
[258] Wachman EM, Newby PK, Vreeland J, et al., The relationship between maternal opioid agonists and psychiatric medications on length of hospitalization for neonatal abstinence syndrome, J. Addict. Med. (2011), 5:293-299.
[259] Patrick SW, Schumacher RE, Benneyworth BD, Krans EE, McAllister JM, Davis MM, Neonatal abstinence syndrome and associated health care expenditures:, United States, 2000-2009, JAMA (2012), 307:1934-1940.
[260] Patrick SW, Davis MM, Lehmann CU, Cooper WO, Increasing incidence and geographic distribution of neonatal abstinence syndrome: United States 2009 to 2012, J. Perinatol (2015), 35:650–5, https://doi.org/10.1038/jp.2015.36.
[261] *Id*.
[262] *See* Amicus Curiae Brief of Healthcare Distribution Management Association in Support of Appellant Cardinal Health, Inc., Cardinal Health, Inc. v. United States Dept. Justice, No. 12-5061 (D.C. Cir. May 9, 2012), 2012 WL 1637016, at *10 [hereinafter Brief of HDMA].

addiction treatment costs, and increased criminal justice expenditures.[263] The aggregate societal cost of the associated heroin epidemic is $50 billion per year.[264]

284. "Counties grappling with rising overdoses face higher costs in emergency call volumes, medical examiner and coroner bills, and overcrowded jails and courtrooms, said Matt Chase, executive director of the National Association of Counties, which represents 3,069 county and local governments."[265] Localities also face rising costs for foster care, as about 75% of the children who are given up or taken by social services have opioid-addicted parents.[266] *Reuters* reports that "the opioid crisis is blowing a hole in small-town America's finances."[267]

CLASS ALLEGATIONS

285. Pursuant to Rule 23 of the Federal Rules of Civil Procedure, Plaintiffs bring this action on behalf of themselves and a proposed class initially defined as: "All municipalities within the Commonwealth of Puerto Rico."

286. Numerosity: The proposed class consists of 78 incorporated towns and cities—too many to practically join in a single action.

287. Common Questions: Common questions of law and fact exist as to all members of the proposed class and predominate over questions affecting only individual class members. These common questions include:

- Whether the Defendants misrepresented the safety and efficacy of prescription opioids;

[263] *Id*. (citing at note 2 Florence CS, Zhou C, Luo F, Xu L, The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013, MED CARE (2016), 54(10):901-906, doi:10.1097/MLR.0000000000000625).
[264] Brian Snyder, Heroin Addiction Costs Us More Than $50 Billion Per Year, Newsweek (June 17, 2017), http://bit.ly/2tGo8eg.
[265] Paula Seligson and Tim Reid, Unbudgeted: How the opioid crisis is blowing a hole in small-town America's finances, Reuters (Sept. 27, 2017), http://reut.rs/2wFo5Bm.
[266] *Id*.
[267] *Id*.

- Whether the Defendants knowingly failed to implement controls against the diversion of opioids from legitimate medical, scientific, or industrial purposes;
- Whether persons who took opioid drugs are at increased risk of severe and permanent injuries, including addiction and overdose;
- Whether Defendants' conduct constitutes a public nuisance;
- Whether Defendants engaged in conduct that violates RICO by associating in an enterprise to allow or facilitate the diversion of opioids from legitimate medical, scientific, or industrial purposes;
- Whether Defendants were and are unjustly enriched by their acts and omissions, at the expense of the Class;
- Whether the Class has been damaged, and if so, the extent of such damages and/or the nature of the equitable relief, statutory damages, or punitive damages to which the Class is entitled; and
- The amount of attorneys' fees, prejudgment interest, and costs of the suit to which the Class is entitled.

288. Typicality: Plaintiffs are members of the putative Class. The claims asserted by the Plaintiffs in this action are typical of the claims of the members of the putative Class, as the claims arise from the same course of conduct by the Defendants and the relief sought is common.

289. Adequacy: Plaintiffs will fairly and adequately represent and protect the interests of the members of the putative Class, as their interests are coincident with, not antagonistic to, the other members of the Class. Plaintiffs have retained counsel competent and experienced in class action litigation. Plaintiffs' counsel specifically has experience litigating some of the largest and most complex class actions.

290. Predominance: Certification of the Class is appropriate pursuant to Fed. R. Civ. P. 23(b)(3) because questions of law or fact common to the respective members of the Class predominate over questions of law or fact affecting only individual members. This predominance makes class litigation superior to any other method available for the fair and efficient adjudication of these claims including consistency of adjudications. Absent a class action it would be highly unlikely that the members of the Class would be able to protect their own interests because the cost of litigation through individual lawsuits might exceed the expected recovery.

291. Superiority: A class action is a superior method for the adjudication of the controversy in that it will permit a large number of claims to be resolved in a single forum simultaneously, efficiently, and without the unnecessary hardship that would result from the prosecution of numerous individual actions and the duplication of discovery, effort, expense, and the burden on the courts that individual actions would create. Puerto Rico's municipalities' resources are already being maxed out in dealing with the aftermath of Hurricane Maria and coordinating recovery efforts, so it's not feasible or efficient for them to devote themselves individually to this litigation. In general, government action to fight the opioid crisis has been limited by "budgetary constraints at the state and Federal levels."[268]

292. In the alternative, the Class should be certified because:

a. The prosecution of separate actions by the individual members of the proposed class would create a risk of inconsistent adjudications, which could establish incompatible standards of conduct for Defendants;

[268] *See* Office of Nat'l Drug Control Policy, Exec. Office of the President, Epidemic: Responding to America's Prescription Drug Abuse Crisis (2011), https://www.ncjrs.gov/pdffiles1/ondcp/rx_abuse_plan.pdf.

b. The prosecution of individual actions could result in adjudications, which as a practical matter, would be dispositive of the interests of non-party class members or which would substantially impair their ability to protect their interests; and

c. Defendants have acted or refused to act on grounds generally applicable to the proposed Class, thereby making appropriate final and injunctive relief with respect to the members of the proposed Class as a whole.

NO STATUTE OF LIMITATIONS BARS PLAINTIFFS' CLAIMS

A. Enforcement of Public Right

293. No statute of limitation can be pleaded against the Plaintiffs or the class, which seeks to enforce strictly public rights.

B. Equitable Estoppel

294. To the extent any statute of limitations defense would apply, Defendants are equitably estopped from relying upon such a defense because they undertook efforts to purposefully conceal their unlawful conduct and fraudulently assure the public, including the Commonwealth, the Plaintiffs, and class members, that they were undertaking efforts to comply with their obligations under the state and federal controlled substances laws, all with the goal of protecting their registered manufacturer or distributor status in the Commonwealth and to continue generating profits. Notwithstanding the allegations set forth above, the Defendants affirmatively assured the public, including the Commonwealth, the Plaintiffs, and Plaintiffs' and class members' communities, that they were working to curb the opioid epidemic.

295. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and assured the public it was being "as effective and

efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."

296. Similarly, McKesson publicly stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."

297. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Opioid Distributors, through their trade associations, HDMA and NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:[269]

a. "HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs, but undertake such efforts as responsible members of society."

b. "DEA regulations that have been in place for more than 40 years require distributors to report suspicious orders of controlled substances to DEA based on information readily available to them (e.g., a pharmacy's placement of unusually frequent or large orders)."

c. "Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that is available to them in the ordering process."

d. "A particular order or series of orders can raise red flags because of its unusual size, frequency, or departure from typical patterns with a given pharmacy."

e. "Distributors also monitor for and report abnormal behavior by pharmacies placing orders, such as refusing to provide business contact information or insisting on paying in cash."

298. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Opioid Distributors not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

[269] Brief for HDMA and NACDS, supra note 81, 2016 WL 1321983, at *3-4, *25.

299. The Opioid Distributors have also concealed and prevented discovery of information, including data from the ARCOS database, that will confirm their identities and the extent of their wrongful and illegal activities.

300. The Opioid Manufacturers distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Opioid Manufacturers invented "pseudoaddiction" and promoted it to an unsuspecting medical community. Opioid Manufacturers provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. Opioid Manufacturers recommended to the medical community that dosages be increased, without disclosing the risks. Opioid Manufacturers spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The medical community, consumers, the Commonwealth, Plaintiffs, and the class were duped by the Opioid Manufacturers' campaign to misrepresent and conceal the truth about the opioid drugs that they were aggressively pushing in the Commonwealth and in Plaintiffs' and class members' communities.

301. Defendants intended that their actions and omissions would be relied upon, including by Plaintiffs and the class. Plaintiffs and the class did not know, and did not have the means to know, the truth due to Defendants' actions and omissions.

302. The Plaintiffs and the class reasonably relied on Defendants' affirmative statements regarding their purported compliance with their obligations under the law and consent orders.

C. Fraudulent Concealment

303. The Plaintiffs' and class members' claims are further subject to equitable tolling, stemming from Defendants' knowingly and fraudulently concealing the facts alleged herein. As

alleged herein, Defendants knew of the wrongful acts set forth above, and had material information pertinent to their discovery, and concealed them from the Plaintiffs and class members, and Plaintiffs' and class members' communities. The Plaintiffs and the class did not know, or could not have known through the exercise of reasonable diligence, of their causes of action, as a result of Defendants' conduct.

304. The purposes of the statutes of limitations period are satisfied because Defendants cannot claim prejudice due to a late filing where the Plaintiffs filed suit promptly upon discovering the facts essential to their claims, described herein, which Defendants knowingly concealed.

305. In light of their statements to the media, in legal filings, and settlements, it is clear that Defendants had actual or constructive knowledge that their conduct was deceptive, in that they consciously concealed the schemes set forth herein.

306. Defendants continually and secretly engaged in their scheme to avoid compliance with their legal obligations. Only Defendants and their agents knew or could have known about Defendants' unlawful actions because Defendants made deliberate efforts to conceal their conduct. As a result of the above, the Plaintiffs was unable to obtain vital information bearing on their claims absent any fault or lack of diligence on their part.

1. The Opioid Distributors Have Misrepresented their Compliance with their Legal Duties

307. The Opioid Distributors have repeatedly misrepresented their compliance with their legal duties under federal, state and Commonwealth law and have wrongfully and repeatedly disavowed those duties in an effort to mislead regulators and the public regarding the Opioid Distributors' compliance with their legal duties.

308. Opioid Distributors have refused to recognize any duty beyond *reporting* suspicious orders. In *Masters Pharmaceuticals*, the HDMA, a trade association run the Opioid Distributors, and the NACDS submitted amicus briefs regarding the legal duty of wholesale distributors. Inaccurately denying the legal duties that the wholesale drug industry has been tragically recalcitrant in performing, they argued as follows:

- The Associations complained that the "DEA has required distributors not only to report suspicious orders, but to *investigate* orders (e.g., by interrogating pharmacies and physicians) and take action to *halt* suspicious orders before they are filled."[270]

- The Associations argued that, "DEA now appears to have changed its position to require that distributors not only *report* suspicious orders, but *investigate* and *halt* suspicious orders. Such a change in agency position must be accompanied by an acknowledgment of the change and a reasoned explanation for it. In other words, an agency must display awareness that it *is* changing position and show that there are good reasons for the new policy. This is especially important here, because imposing intrusive obligation on distributors threatens to disrupt patient access to needed prescription medications."[271]

- The Associations alleged (inaccurately) that nothing "requires distributors to investigate the legitimacy of orders, or to halt shipment of any orders deemed to be suspicious."[272]

- The Association complained that the purported "practical infeasibility of requiring distributors to investigate and halt suspicious orders (as well as report them) underscores the importance of ensuring that DEA has complied with the APA before attempting to impose such duties."[273]

- The Associations alleged (inaccurately) that "DEA's regulations [] sensibly impose[] a duty on distributors simply to *report* suspicious orders, but left it to DEA and its agents to investigate and halt suspicious orders."[274]

- Also inaccurately, the Associations argued that, "[i]mposing a duty on distributors – which lack the patient information and the necessary medical

[270] Brief for HDMA and NACDS, supra note 81, 2016 WL 1321983, at *4–5.
[271] *Id*. at *8 (citations and quotation marks omitted).
[272] *Id*. at *14.
[273] *Id*. at *22.
[274] *Id*. at *24–25.

> expertise – to investigate and halt orders may force distributors to take a shot-in-the-dark approach to complying with DEA's demands."[275]

309. The position taken by the trade groups is emblematic of the position taken by the Opioid Distributors in a futile attempt to deny their legal obligations to prevent diversion of the dangerous drugs.[276]

310. The Court of Appeals for the District of Columbia recently issued its opinion affirming that a wholesale drug distributor does, in fact, have duties beyond reporting.[277] The D.C. Circuit Court upheld the revocation of Master Pharmaceutical's license and determined that DEA regulations require that in addition to reporting suspicious orders, distributors must "decline to ship the order, or conduct some 'due diligence' and—if it is able to determine that the order is not likely to be diverted into illegal channels—ship the order."[278] Master Pharmaceutical was in violation of legal requirements because it failed to conduct necessary investigations and filled suspicious orders.[279] A distributor's investigation must dispel all the red flags giving rise to suspicious circumstance prior to shipping a suspicious order. *Id*. at 226. The Circuit Court also rejected the argument made by the HDMA and NACDS (quoted above), that, allegedly, the DEA had created or imposed new duties. *Id*. at 220.

311. Wholesale Distributor McKesson has recently been forced to specifically admit to breach of its duties to monitor, report, and prevent suspicious orders. Pursuant to an Administrative Memorandum of Agreement ("2017 Agreement") entered into between McKesson and the DEA in January 2017, McKesson admitted that, at various times during the period from January 1, 2009 through the effective date of the Agreement (January 17, 2017) it

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[275] *Id*. at 26.
[276] *See id.* at *3 (arguing the wholesale distributor industry "does not know the rules of the road because" they claim (inaccurately) that the "DEA has not adequately explained them").
[277] *Masters Pharm., Inc. v. Drug Enf't Admin.*, 861 F.3d 206 (D.C. Cir. 2017).
[278] *Id*. at 212.
[279] *Id.* at 218–19, 226.

"did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters."[280]

312. Further, the 2017 Agreement specifically finds that McKesson "distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a)."[281] McKesson admitted that, during this time period, it "failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq*., at the McKesson Distribution Centers" including the McKesson Distribution Center located in "Washington Courthouse, Ohio."[282] Due to these violations, McKesson agreed that its authority to distribute controlled substances from the Washington Courthouse, Ohio facility (among other facilities) would be partially suspended.[283]

313. The 2017 Memorandum of Agreement followed a 2008 Settlement Agreement in which McKesson also admitted failure to report suspicious orders of controlled substances to the DEA.[284] In the 2008 Settlement Agreement, McKesson "recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA," but had failed to do

[280] *See* Administrative Memorandum of Agreement between the U.S. Dep't of Justice, the Drug Enf't Admin., and the McKesson Corp. (Jan. 17, 2017), https://www.justice.gov/opa/press-release/file/928476/download.
[281] *Id*. at 4.
[282] *Id*.
[283] *Id*. at 6.
[284] *Id*. at 4.

so.[285] The 2017 Memorandum of Agreement documents that McKesson continued to breach its admitted duties by "fail[ing] to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations."[286] As a result of these violations, McKesson was fined and required to pay to the United States $150,000,000.[287]

314. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

315. Because of the Opioid Distributors' refusal to abide by their legal obligations, the DEA has repeatedly taken administrative action to attempt to force compliance. For example, in May 2014, the United States Department of Justice, Office of the Inspector General, Evaluation and Inspections Divisions, reported that the DEA issued final decisions in 178 registrant actions between 2008 and 2012.[288] The Office of Administrative Law Judges issued a recommended decision in a total of 117 registrant actions before the DEA issued its final decision, including 76 actions involving orders to show cause and 41 actions involving immediate suspension orders.[289] These actions include the following:

- On April 24, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the AmerisourceBergen Orlando, Florida distribution center ("Orlando Facility") alleging failure to maintain effective controls against

[285] *Id*.
[286] *Id*.; *see* also Settlement Agreement and Release between the U.S. and McKesson Corp., at 5 (Jan. 17, 2017) [hereinafter 2017 Settlement Agreement and Release] ("McKesson acknowledges that, at various times during the Covered Time Period [2009-2017], it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA."), https://www.justice.gov/opa/press-release/file/928471/download.
[287] *See* 2017 Settlement Agreement and Release, at 6.
[288] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, The Drug Enforcement Administration's Adjudication of Registrant Actions 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.
[289] *Id*.

diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration;

- On November 28, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Auburn, Washington Distribution Center ("Auburn Facility") for failure to maintain effective controls against diversion of hydrocodone;

- On December 5, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of hydrocodone;

- On December 7, 2007, the DEA issued an *Order to Show Cause and Immediate Suspension Order* against the Cardinal Health Swedesboro, New Jersey Distribution Center ("Swedesboro Facility") for failure to maintain effective controls against diversion of hydrocodone;

- On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Stafford, Texas Distribution Center ("Stafford Facility") for failure to maintain effective controls against diversion of hydrocodone;

- On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program";

- On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility");

- On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health Lakeland, Florida Distribution Center ("Lakeland Facility") for failure to maintain effective controls against diversion of oxycodone;

- On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland, Florida Distribution Center; and

- On January 5, 2017, McKesson Corporation entered into an *Administrative Memorandum Agreement* with the DEA wherein it agreed to pay a $150 million civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora CO, Aurora IL, Delran NJ, LaCrosse WI, Lakeland FL, Landover MD, La Vista NE, Livonia MI, Methuen MA, Sante Fe Springs CA, Washington Courthouse OH and West Sacramento CA.

316. Rather than abide by their non-delegable duties under public safety laws, the Opioid Distributors, individually and collectively through trade groups in the industry, pressured the U.S. Department of Justice to "halt" prosecutions and lobbied Congress to strip the DEA of its ability to immediately suspend distributor registrations. The result was a "sharp drop in enforcement actions" and the passage of the "Ensuring Patient Access and Effective Drug Enforcement Act" which, ironically, raised the burden for the DEA to revoke a distributor's license from "imminent harm" to "immediate harm" and provided the industry the right to "cure" any violations of law before a suspension order can be issued.[290]

317. In addition to taking actions to limit regulatory prosecutions and suspensions, the Opioid Distributors undertook to fraudulently convince the public that they were complying with their legal obligations, including those imposed by licensing regulations. Through such statements, the Opioid Distributors attempted to assure the public they were working to curb the opioid epidemic.

[290] *See* Lenny Bernstein & Scott Higham, Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea-slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e- 7f71-11e6-8d13-d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation- of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9- a05d3c21f7cf_story.html; Eric Eyre, DEA Agent: "We Had No Leadership" in WV Amid Flood of Pain Pills, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership- in-wv-amid-flood-of-pain-pills-.

318. For example, a Cardinal Health executive claimed that it uses "advanced analytics" to monitor its supply chain, and represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity."[291] Given the sales volumes and the company's history of violations, this executive was either not telling the truth, or, if Cardinal Health had such a system, it ignored the results.

319. Similarly, Defendant McKesson publicly stated that it has a "best-in- class controlled substance monitoring program to help identify suspicious orders," and claimed it is "deeply passionate about curbing the opioid epidemic in our country."[292] Again, given McKesson's historical conduct, this statement is either false, or the company ignored outputs of the monitoring program.

320. By misleading the public about the effectiveness of their controlled substance monitoring programs, the Opioid Distributors successfully concealed the facts sufficient to arouse suspicion of the claims that the Plaintiffs now assert. The Plaintiffs did not know of the existence or scope of Defendants' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

321. Meanwhile, the opioid epidemic rages unabated in the Nation, the State, Commonwealth, and in Plaintiffs' and class members' communities.

322. The epidemic still rages because the fines and suspensions imposed by the DEA do not change the conduct of the industry. The distributors, including the Opioid Distributors, pay fines as a cost of doing business in an industry that generates billions of dollars in annual

[291] Lenny Bernstein et al., How Drugs Intended for Patients Ended Up in the Hands of Illegal Users: "No One Was Doing Their Job," Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/how-drugs-intended-for- patients-ended-up-in-the-hands-of-illegal-users-no-one-was-doing-their- job/2016/10/22/10e79396-30a7-11e6-8ff7-7b6c1998b7a0_story.html.

[292] Scott Higham et al., Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse, Wash. Post, Dec. 22, 2016, https://www.washingtonpost.com/investigations/key-officials-switch-sides-from-dea-to-pharmaceutical-industry/2016/12/22/55d2e938-c07b-11e6-b527- 949c5893595e_story.html.

revenue. They hold multiple DEA registration numbers and when one facility is suspended, they simply ship from another facility.

323. The wrongful actions and omissions of the Opioid Distributors which have caused the diversion of opioids and which have been a substantial contributing factor to and/or proximate cause of the opioid crisis are alleged in greater detail in Plaintiffs' racketeering allegations below.

324. The Opioid Distributors have abandoned their duties imposed under federal state and Commonwealth law, taken advantage of a lack of DEA law enforcement, and abused the privilege of distributing controlled substances in the Commonwealth and Plaintiffs' and class members' communities.

2. The Opioid Manufacturers Fraudulently Concealed Their Misconduct

325. The Opioid Manufacturers, both individually and collectively, made, promoted, and profited from their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their misrepresentations were false and deceptive. The history of opioids, as well as research and clinical experience establish that opioids are highly addictive and are responsible for a long list of very serious adverse outcomes. The FDA warned the Opioid Manufacturers of this, and the Opioid Manufacturers had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and death – all of which clearly described the harm from long-term opioid use and that patients were suffering from addiction, overdose, and death in alarming numbers. More recently, the FDA and CDC have issued pronouncements, based on medical evidence, that conclusively expose the falsity of Opioid Manufacturers' misrepresentations, and Endo and Purdue have recently entered agreements in New York prohibiting them from making some of the same misrepresentations described in this Complaint.

326. At all times relevant to this Complaint, the Opioid Manufacturers took steps to avoid detection of and to fraudulently conceal their deceptive marketing and unlawful, unfair, and fraudulent conduct. For example, the Opioid Manufacturers disguised their role in the deceptive marketing of chronic opioid therapy by funding and working through third parties like Front Groups and key opinion leaders. The Opioid Manufacturers purposefully hid behind the assumed credibility of these individuals and organizations and relied on them to vouch for the accuracy and integrity of the Opioid Manufacturers' false and deceptive statements about the risks and benefits of long-term opioid use for chronic pain. The Opioid Manufacturers also never disclosed their role in shaping, editing, and approving the content of information and materials disseminated by these third parties. The Opioid Manufacturers exerted considerable influence on these promotional and "educational" materials in emails, correspondence, and meetings with key opinion leaders, Front Groups, and public relations companies that were not, and have not yet become, public. For example, PainKnowledge.org, which is run by the National Initiative on Pain Control, did not disclose Endo's involvement. Other Opioid Manufacturers, such as Purdue and Janssen, ran similar websites that masked their own role.

327. Finally, the Opioid Manufacturers manipulated their promotional materials and the scientific literature to make it appear that these documents were accurate, truthful, and supported by objective evidence when they were not. The Opioid Manufacturers distorted the meaning or import of studies they cited and offered them as evidence for propositions the studies did not support. The Opioid Manufacturers invented "pseudoaddiction" and promoted it to an unsuspecting medical community. The Opioid Manufacturers provided the medical community with false and misleading information about ineffectual strategies to avoid or control opioid addiction. The Opioid Manufacturers recommended to the medical community that dosages be

increased, without disclosing the risks. The Opioid Manufacturers spent millions of dollars over a period of years on a misinformation campaign aimed at highlighting opioids' alleged benefits, disguising the risks, and promoting sales. The lack of support for the Opioid Manufacturers' deceptive messages was not apparent to medical professionals who relied upon them in making treatment decisions, nor could it have been detected by the Plaintiffs and class members or Plaintiffs' and class members' communities. Thus, the Opioid Manufacturers successfully concealed from the medical community, patients, and health care payors facts sufficient to arouse suspicion of the claims that the Plaintiffs now assert. Plaintiffs did not know of the existence or scope of the Opioid Manufacturers' industry-wide fraud and could not have acquired such knowledge earlier through the exercise of reasonable diligence.

LEGAL CAUSES OF ACTION

COUNT 1. PUBLIC NUISANCE (Against all Defendants)

328. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth here.

329. Puerto Rico law provides, "Anything which is injurious to health … so as to interfere with the comfortable enjoyment of life or property, or that is a nuisance to the wellbeing of a neighborhood, or to a large number of persons … constitute a nuisance and the subject of an action. Such action may be brought by any person, public agency or municipality whose property is injuriously affected or whose personal enjoyment is lessened by the nuisance, and by the judgment the nuisance may be enjoined or abated, as well as damages recovered." 32 L.P.R.A. § 2761.

330. Defendants' conduct has caused unreasonable and substantial interference with public health and comfortable enjoyment of life and property, such as by increasing opioid

overdoses, addiction, HIV and Hepatitis C infections, public healthcare costs, law enforcement and jail costs, and the cost of childcare for wards of the Commonwealth. Plaintiffs and the class are injured by paying these costs.

331. Defendants' conduct was a substantial factor in causing Plaintiffs and the class to pay these costs. The Opioid Manufacturers engaged in a decades-long misinformation campaign to convince the public and doctors that opioids were safe and effective for long-term pain, when in reality, opioids are extremely addictive and are ineffective in the long-term as patients build a tolerance. The Opioid Distributors covered up the sale of prescription opioids to suspicious buyers, rather than report these sales to authorities and stop shipment. Both the Opioid Manufacturers' and Distributors' conduct was a substantial factor in causing the opioid epidemic.

332. By causing dangerously addictive drugs to flood Plaintiffs' and the class's communities, the Defendants have injuriously affected rights common to the general public, such as the rights of the people to public health, public safety, public peace, public comfort, and public convenience. The public nuisance caused by Defendants' conduct has caused substantial annoyance, inconvenience, and injury to the public.

333. Defendants have committed a continuing course of conduct that injuriously affects the safety, health, and morals of the people of the Plaintiffs' and class members' communities.

334. The presence of diverted prescription opioids in Plaintiffs' and class members' communities, and the consequence of prescription opioids having been diverted in Plaintiffs' and class members' communities, is the direct and proximate result of the Defendants' failure to

report suspicious orders to law enforcement and failure to stop shipment on orders that are suspicious or potentially suspicious.

335. Stemming the flow of illegally distributed prescription opioids, and abating the nuisance caused by the illegal flow of opioids, will help to alleviate this problem, save lives, prevent injuries and make Plaintiffs' and class members' communities a safer place to live.

336. Plaintiffs seek an injunction and to recover the cost of abating the nuisance, as available under 32 L.P.R.A. § 2761, 32 L.P.R.A. § 3532, and 3 L.P.R.A. § 182.

COUNT 2. RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT 18 U.S.C. 1961, *et seq.*
(Against All Defendants)

337. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein.

338. Defendants are persons, within the meaning of RICO, because they hold a legal or beneficial interest in property (e.g., prescription drugs).

339. Defendants violated RICO, 8 U.S.C. § 1962, by conducting or participating in the affairs of an enterprise that derived income from a pattern of racketeering activity, or by conspiring to do the same.

A. The Opioid Misinformation Enterprise

340. The Opioid Manufacturers, and their key opinion leaders and Front Groups, were part of an associated-in-fact enterprise within the meaning of RICO (18 U.S.C. §§ 1961 (4) and 1962 (c)), because they had a common purpose of, through unlawful means, engaging in a misinformation campaign to expand the market for opioids. There was a relationship between the Opioid Manufacturers as common sponsors of key opinion leaders, such as Dr. Russell Portenoy and Dr. Lynn Webster, and common members of and contributors to influential Front Groups,

such as American Pain Foundation and American Academy of Pain Medicine. The duration of the enterprise spanned years, from the 1990s until the present time, providing more than sufficient time to pursue the enterprise's goals.

341. Despite their association as part of an enterprise, the Opioid Manufacturers and their captured key opinion leaders and Front Groups are distinct entities with different organizational structures.

342. The enterprise engaged in interstate commerce by transacting business and marketing across state lines.

343. The Opioid Manufacturers participated in the conduct of the enterprise by knowingly implementing the enterprise's agenda of spreading misinformation about whether opioids should be used to treat long-term pain.

344. The Opioid Manufacturers knowingly participated in a scheme to obtain money or property through use of false or fraudulent pretenses. The scheme sought to convince doctors and patients that opioids were safe and effective for long-term pain, relatively non-addictive, and should be liberally prescribed for all types of pain. Through their common sponsorship and funding of key opinion leaders and Front Groups, the Opioid Manufacturers sought to spread the false messages that: opioids were safe and effective for treating chronic pain; opioids posed only a small (less than 1%) risk of addiction; drug-seeking behavior was actually a sign of under-treated pain, not of a substance abuse problem (i.e., the concept of pseudoaddiction); and screening tools could accurately predict who was high or low risk for addiction, allowing doctors to prescribe opioids to low risk patients without fear.

345. In reality, as the medical community had long known and understood prior to the Opioid Manufacturers' misinformation campaign, prescription opioids are a highly addictive

form of synthetic heroin that is not effective for treating chronic pain, as patients develop a tolerance over time, necessitating that patients take larger and larger doses to get the same effect. As the CDC has stated, the larger the dose, the higher the risk of addiction. The widely cited study purporting to show that only 1% of long-term opioid patients become addicted was a complete fiction. The "study" was nothing more than a short letter to the editor discussing addiction to morphine and other opioids administered in an in-patient setting, such as after surgery. Use longer than the duration of the patient's hospital stay was *not* studied. Nevertheless, Dr. Russell Portenoy, as part of the opioid-misinformation enterprise, used the enterprise's funds to turn this 1% statistic into accepted medical gospel. Dr. Lynn Webster likewise, as part of the enterprise, used funds from the enterprise to popularize the concept of pseudoaddiction, instructing doctors that patients with drug seeking behavior were actually in need of more opioids, not less. In reality, pill-seeking behavior was just a classic sign of addiction. And screening tools are not an effective way to ensure that patients do not become addicted to opioids. Rather, one of the best way to prevent addiction is to prescribe opioids carefully, only as a last resort, in limited circumstances, and for as short a duration as possible. With a 3-day supply of opioids, only 10% of patients are likely to become long-term users.[293] With a 10-day supply, the number doubles: 20% will become long-term users.[294] "The longer you use opioids, the greater the risks—and the risks rise fast."[295]

346. The above representations were material because they were capable of influencing a doctor of ordinary intelligence to prescribe opioids more freely to patients with chronic pain. Many doctors and health authorities rely on the manufacturers' guidelines for the medications in

[293] Beth Mole, With a 10-day supply of opioids, 1 in 5 become long-term users, ArsTechnica (Mar. 18, 2017), http://bit.ly/2nDlCmL.
[294] *Id*.
[295] *Id*.

deciding how to prescribe them. And, many doctors rely on information they receive from other doctors, such as key opinion leaders, to inform how they prescribe. Patients relied on their doctors' advice, as well as the representations conveyed to them by the drug makers.

347. The Opioid Manufacturers intended to deceive doctors and patients about the safety and efficacy of opioids in order to substantially expand the market for opioids, opening up more profit potential for the Opioid Manufacturers' drugs.

348. In furtherance of the enterprise's agenda, the Opioid Manufacturers engaged in two or more predicate acts of mail and/or wire fraud.

349. The Opioid Manufacturers used the mail and/or interstate wire communications to deliver the enterprise's false and misleading representations. Sections B and C of the complaint contain numerous specific examples of misleading videos, audio, pamphlets, guidelines, or other material that the Opioid Manufacturers conveyed to doctors and their patients using the U.S. mail or public internet (i.e. interstate wires) in furtherance of the general scheme. For example, the American Pain Foundation, an Opioid Manufacturer front group, engaged in a significant multimedia campaign – through radio, television and the internet – to educate patients about their "right" to pain treatment, namely opioids. And Dr. Portenoy's infamous consensus paper, which said opioids were safe to prescribe for chronic pain, with an addiction rate below 1%, was distributed through American Academy of Pain Medicine's website until 2011.

350. There is a pattern of two or more predicate acts because the acts were related and continuous. All mail and wire fraud were related to the same scheme to spread misinformation about opioids in order to convince doctors and patients to widely prescribe and use opioids for chronic pain. The acts occurred continuously from the launch of the Opioid Manufacturers branded opioid drugs in or around the 1990s until the present time.

351. The Opioid Manufacturers' behavior poses a threat of continued racketeering activity, as they have not ceased making false and misleading representations concerning opioids and have tried to discount their role in creating the opioid crisis.

352. Plaintiffs and the class are "persons," within the meaning of RICO, and have been injured in their business or property by: paying directly for costs associated with the opioid crisis, such as hospital admissions and other medical costs, police, firefighters, and emergency medical technician calls, as well as the loss in productivity of Plaintiffs and the class's residents due to substance abuse, addiction, and death.

353. Plaintiffs' and the class's injuries and financial damages were proximately caused by the conduct constituting the RICO violation because such conduct caused the opioid epidemic.

354. Plaintiffs and the class seek three times actual damages, injunctive relief, costs, and attorneys' fees, pursuant to 18 U.S.C. § 1964(c).

B. The Opioid Diversion Enterprise

355. The Opioid Distributors were part of an associated-in-fact enterprise within the meaning of RICO (18 U.S.C. §§ 1961 (4) and 1962 (c)), because they had a common purpose of, through unlawful means, engaging in a subversion campaign to ensure that the DEA would not be able to close down their opioid distribution warehouses that were unlawfully supplying problem prescribers and pharmacies with millions of dollars in opioids that would be diverted into the illegal market. There was a relationship between the Opioid Distributors not only through their business ties, but also through their joint lobbying efforts to hamper or hamstring the DEA. The duration of the enterprise spanned years, from the 1990s until the present time, providing more than sufficient time to pursue the enterprise's goals.

356. Alternatively, the Opioid Distributors were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance is a distinct legal entity that satisfies the definition of a RICO enterprise. The Healthcare Distribution Alliance is a non-profit corporation formed under the laws of the District of Columbia. As a non-profit corporation, Healthcare Distribution Alliance qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity. The Opioid Distributors are members of Healthcare Distribution Alliance; each Opioid Distributor has one of its executives on Healthcare Distribution Alliance's board of directors; and each Opioid Distributor acted through Healthcare Distribution Alliance.

357. Despite their association as part of an enterprise, the Opioid Distributors and their lobbying organizations, such as Healthcare Distribution Alliance, are distinct entities with different organizational structures.

358. The enterprise engaged in interstate commerce by transacting business and marketing across state lines.

359. The Opioid Distributors participated in the conduct of the enterprise by knowingly implementing the enterprise's agenda.

360. The Opioid Distributors knowingly participated in a scheme to obtain money or property through use of false or fraudulent pretenses. The scheme sought to misrepresent the Opioid Distributors' compliance with their duties to report and stop suspicious orders and to hamstring the DEA's investigation of and ability to investigate the Opioid Distributors' compliance with their legal obligations, so that the Opioid Distributors could continue to profit

from the diversion of opioids that they knew, or should have known, were ending up in the illegal market.

361. In reality, the Opioid Distributors were not complying with their legal obligations and had no intention to do so. The Opioid Distributors willfully ignored blatant red flags that certain pharmacies were diverting the Opioid Distributors' drugs into the illegal market. For example, "On Oct. 5, 2010, when Cardinal investigator Vincent Moellering visited Gulf Coast Medical Pharmacy, a drugstore in Fort Myers, Fla., he found evidence of diversion everywhere, records show, including suspicious customers who came in groups to fill their prescriptions. The pharmacy's owner told Moellering that he could sell even more narcotics if Cardinal would supply them, according to Moellering's report … Moellering labeled the drugstore 'high risk' and wrote: 'I am not convinced that the owner is being forthright pertaining to his customers' origin or residence. I have requested permission to contact DEA to resolve this issue.' But Cardinal didn't notify the agency or cut off Gulf Coast's drug supply, the DEA contends. Instead, the shipments kept going out."[296]

362. The above representations were material because the DEA and other government officials relied on them in not revoking the Opioid Manufacturers' registration permitting them to distribute prescription opioids throughout the United States. McKesson, for example, avoided revocation of five of its warehouses' registrations by representing, along with other distributors, that it was doing the best that it could in terms of compliance.

363. The Opioid Distributors intended to mislead government officials about their compliance programs so that they could continue to profit immensely from the diversion of their opioid drugs into the unlawful marketplace.

[296] Bernstein, How drugs intended for patients ended up in the hands of illegal users, *supra* note 169.

364. In furtherance of the enterprise's agenda, the Opioid Distributors engaged in two or more predicate acts of mail and/or wire fraud.

365. The Opioid Distributors used the mail and/or interstate wire communications to deliver the enterprise's false and misleading representations to government officials and the public. For example, two lobbyists for Cardinal Health, "former deputy attorneys general, Jamie S. Gorelick, who served in the Clinton administration, and Craig S. Morford, who served in the George W. Bush administration" used interstate telephone wires to separately contact the DEA, telephone records show, says the *Washington Post*.[297] The lobbyists' goal was to impede or stop Rannazzisi's Distributor Initiative that was attempting to enforce distributors' obligations to report and stop suspicious shipments of opioids.[298]

366. There is a pattern of two or more predicate acts because the acts were related and continuous. All mail and wire fraud were in furtherance of the same scheme to misrepresent their ability to comply with their federal obligations to report and stop suspicious orders of opioids. The acts occurred continuously from in or around the 1990s until the present time.

367. The Opioid Distributors' behavior poses a threat of continued racketeering activity, as they have not ceased making false and misleading representations to government officials and to the public.

368. Plaintiffs and the class are "persons," within the meaning of RICO, and have been injured in their business or property by: paying directly for costs associated with the opioid crisis, such as hospital admissions and other medical costs, police, firefighters, and emergency medical technician calls, as well as the loss in productivity of Plaintiffs and the class's residents due to substance abuse, addiction, and death.

[297] Lenny Bernstein and Scott Higham, Investigation: The DEA slowed enforcement while the opioid epidemic grew out of control, *supra* note 171.
[298] *Id*.

369. Plaintiffs' and the class's injuries and financial damages were proximately caused by the conduct constituting the RICO violation because such conduct fueled the opioid epidemic.

370. Plaintiffs and the class seek three times actual damages, injunctive relief, costs, and attorneys' fees, pursuant to 18 U.S.C. § 1964(c).

COUNT 3. UNJUST ENRICHMENT (Against All Defendants)

371. Plaintiffs incorporate the allegations within all prior paragraphs within this complaint as if they were fully set forth herein.

372. "Unjust enrichment is a doctrine based on equity of general application to all situations where its nonapplication would perpetuate the inequity that someone may unjustly enrich himself at the expense of another." *Medina & Medina v. Country Pride Foods Ltd.*, 631 F. Supp. 293, 302 (D.P.R. 1986) (internal quotation marks omitted). Defendants are liable for unjust enrichment because there is: 1) existence of enrichment; 2) a correlative loss; 3) nexus between loss and enrichment; 4) enrichment would work an injustice; and 5) absence of a public policy that would prevent application of unjust enrichment doctrine. *Hatton v. Mun. de Ponce*, No. RE-91-37, 1994 WL 909605 (P.R. Jan. 12, 1994).

373. The Opioid Manufacturers were enriched by promoting the falsity that opioids are safe, non-addictive, and effective for long-term pain. Members of Plaintiffs' and the class's communities were misled into prescribing and/or taking opioid medications that they would not otherwise have taken because these medications have adverse side effects, are highly addictive, and are not effective for long-term pain management, since patients develop a tolerance to opioid medications over time.

374. The Opioid Distributors were enriched by their conduct of concealing and refusing to report suspicious orders of opioids from prescribers and pharmacies. These pharmacies and prescribers diverted millions of opioid pills to the black market, and used

illegally acquired funds to pay the Opioid Distributors hundreds of millions, if not billions, of dollars.

375. Plaintiffs and class members suffered a loss. Their communities were subjected to an opioid epidemic, which increased addiction rates to prescription opioids and heroin, overdose rates, rates of asthma-related complications, and rates of blood-borne illnesses. Plaintiffs and class members were forced to expend substantial resources fighting the opioid epidemic in their communities, such as the cost of increased hospitalizations, law enforcement, criminal justice, and social services.

376. There is a nexus between Plaintiffs' and the class's losses and the Defendants' enrichment. The Opioid Manufacturers caused the opioid epidemic by ensuring that opioids would be widely prescribed for chronic pain, and the Opioid Distributors fanned the flames of the epidemic by covering for pharmacies and prescribers who had suspicious ordering patterns due to their black market activities. This opioid crisis directly led to Plaintiffs' and the class's losses.

377. To permit Defendants to maintain their pecuniary gains from their wrongful conduct would work an injustice. Inequity would result because Defendants should not be permitted to profit from their role in causing the worst drug epidemic in U.S. history. A bad precedent would be set if pharmaceutical companies and distributors are permitted to profit from lying to the public about the safety and efficacy of their medications and knowingly selling prescription drugs to pharmacies and prescribers whose ordering patterns indicate that they are re-selling these drugs on the black market.

378. There is no public policy in Puerto Rico that would prevent application of unjust enrichment doctrine. On information and belief, no contract exists between Plaintiffs or class

members and the Defendants that would govern rather than quasi-contractual theories. And, if anything, public policy weighs in favor of restoring to Puerto Rico's municipalities the money that Defendants have sucked out of their budgets and communities by causing the opioid crisis.

379. By reason of the foregoing, Defendants must disgorge their unjustly acquired revenues and provide restitution to the Plaintiffs and the class.

COUNT 4. NEGLIGENCE (Against All Defendants)

380. Plaintiffs incorporate the allegations within all prior paragraphs within this complaint as if they were fully set forth herein.

381. "Puerto Rico tort law imposes responsibility for damages caused by negligence or fault. The necessary elements to prevail in such a tort action are: (1) a negligent act or omission, (2) damages, and (3) a causal relationship between them." *Acevedo-Reinoso v. Iberia Lineas Aereas de Espana S.A.*, 449 F.3d 7, 15 (1st Cir. 2006) (citations, internal quotation marks, and bracketing removed); *see also* 31 L.P.R.A. § 5141 ("A person who by an act or omission causes damage to another through fault or negligence shall be obliged to repair the damage so done.").

382. Defendants have a duty to exercise reasonable care in the sale and distribution of opioids.

383. The Opioid Manufacturers breached this duty by failing to exercise reasonable care in instructing doctors how and when to prescribe opioids. Specifically, Opioid Manufacturers told doctors that they should prescribe opioids for chronic pain, even though for the vast majority of chronic-pain patients, the risks from opioids outweigh the potential benefits. The Opioid Manufacturers had a duty under federal and Puerto Rican law to disclose to doctors the true risk of prescribing opioids. Doctors reasonably relied on the Opioid Manufacturers' assertions that opioids were safe, non-addictive, and effective for long-term pain. Doctors had a duty to their patients to do no harm. Patients reasonably relied on their doctors not to prescribe

them a medication that was more likely to harm them than help them. As a result of patients' reliance, the opioid epidemic occurred and caused harm to Plaintiffs and the class.

384. The Opioid Distributors breached their duty of reasonable care by failing to flag suspicious orders of prescription opioids and stop shipment. The opioid epidemic was a foreseeable result of the Opioid Distributors' failure to act. The opioid epidemic caused Plaintiffs and the class harm.

385. The Opioid Distributors also breached their duty of reasonable care by failing to disclose to federal and Puerto Rican law enforcement that suspicious orders of prescription opioids were being made. The Opioid Distributors have an obligation under federal law to monitor orders and disclose this information to the Drug Enforcement Administration, and have a duty under Puerto Rican law to follow all federal obligations in their distribution of Schedule II prescription drugs. The opioid epidemic occurring or being exacerbated was a foreseeable result of the Opioid Distributors failure to act. Plaintiffs and the class were harmed as a result of the opioid epidemic.

386. Plaintiffs and the class were harmed by the lost productivity of their residents and by paying increased cost for drug treatment and rehabilitation, other medical costs of overdose, withdrawal, asthma sufferers, and transferable diseases, increased cost of law enforcement, criminal justice, and criminal punishment, and increased cost for social services provided to wards of the Commonwealth.

387. The opioid crisis was a reasonably foreseeable consequence of the Defendants' acts and omissions, and Plaintiffs' and the class's harm was a reasonably foreseeable result of the opioid crisis.

388. Sabana Grande and Cayey, and the class, are without fault in regards to the injuries they suffered as a result of Defendants' conduct.

PUNITIVE DAMAGES

389. Plaintiffs re-allege all paragraphs of this complaint as if set forth fully herein.

390. By engaging in the above-described intentional and/or unlawful acts or practices, Defendants acted with actual malice, wantonly, and oppressively. Defendants acted with conscious disregard to the rights of others and/or in a reckless, wanton, willful, or grossly negligent manner. Defendants acted with a prolonged indifference to the adverse consequences of their actions and/or omissions. Defendants acted with a conscious disregard for the rights and safety of others in a manner that had a great probability of causing substantial harm. Defendants acted toward the Plaintiffs and class with fraud, oppression, and/or malice, and/or were grossly negligent in failing to perform the duties and obligations imposed upon them under applicable federal, state and Commonwealth statutes, and common law.

391. Defendants were selling and/or manufacturing dangerous drugs statutorily categorized as posing a high potential for abuse and severe dependence. Thus, Defendants knowingly traded in drugs that presented a high degree of danger if prescribed incorrectly or diverted to other than legitimate medical, scientific, or industrial channels. Because of the severe level of danger posed by, and indeed visited upon the Commonwealth and Plaintiffs' and class members' communities by these dangerous drugs, Defendants owed a high duty of care to ensure that these drugs were only used for proper medical purposes. Defendants chose profit over prudence and the safety of the communities, and an award of punitive damages is appropriate, as punishment and deterrence.

392. By engaging in the above-described wrongful conduct, Defendants also engaged in willful misconduct and gross negligence, and exhibited an entire want of care that would raise the presumption of a conscious reckless indifference to consequences.

RELIEF

393. WHEREFORE, the Plaintiffs respectfully pray that this Court grant the following relief:

394. An order certifying this action as a class action under Fed. R. Civ. P. 23, defining the Class as requested herein, appointing Plaintiffs' attorneys as Class Counsel, and finding that Plaintiffs are proper representatives of the Class requested herein.

395. Entering Judgment in favor of the Plaintiffs and class in a final order against each of the Defendants;

396. Enjoining the Defendants and their employees, officers, directors, agents, successors, assignees, merged or acquired predecessors, parent or controlling entities, subsidiaries, and all other persons acting in concert or participation with them, from engaging in unlawful sales and/or distribution of prescription opioid pills and ordering temporary, preliminary or permanent injunction;

397. Order that Defendants compensate the Plaintiffs and class for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;

398. Order Defendants to fund an "abatement fund" for the purposes of abating the opioid nuisance;

399. Awarding actual damages, treble damages, injunctive and equitable relief, forfeiture as deemed proper by the Court, and attorney fees and all costs and expenses of suit pursuant to Plaintiffs' racketeering claims;

400. Awarding the Plaintiffs and class the damages caused by the opioid epidemic, including:

a. costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths;

b. costs for providing treatment, counseling, and rehabilitation services;

c. costs for providing treatment of infants born with opioid-related medical conditions;

d. costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; and

e. costs associated with law enforcement and public safety relating to the opioid epidemic.

401. Awarding judgment against the Defendants requiring Defendants to pay punitive damages;

402. Granting the Plaintiffs and class:

a. The cost of investigation, reasonable attorneys' fees, and all costs and expenses;

b. Pre-judgment and post-judgment interest; and,

c. All other relief as provided by law and/or as the Court deems appropriate and just.

JURY TRIAL DEMAND

403. Plaintiffs hereby request trial by jury for all issues so triable.

Respectfully submitted,

/s/ Douglas Sanders

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